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Articles should be original contributions, not previously published and should not be under consideration to publish elsewhere. Articles should be between 4 000 and 5 000 words, set at 12 point font, in Times New Roman, with 1 ½ lines spacing. An abstract of 150–200 words must be included.

Spelling

UK English spelling is preferred; and should conform to the most recent edition of the Concise Oxford English Dictionary.

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Footnotes should be avoided and their content must be incorporated into the text. If notes are unavoidable, they must be brief and to the point. Convert them to endnotes.

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FROM THE MANAGING EDITOR

This issue, the second of the *African Journal of Intellectual Property* (AJIP) tackles a diverse range of topics from Geographical Indication in sub-Saharan Africa, to Africa's intellectual property systems, access and innovation in patent enforcement, employer ownership of patent and design rights, and the suitability of intellectual property laws for protecting traditional knowledge in Africa. The contributing authors come from equally diverse backgrounds; legal practitioners including a magistrate, and academics including a professor, PhD students and a researcher.

In their article, **Chinedu et al.** argue that whereas the emergence of Protected Geographical Indication as an intellectual property right has brought opportunities and challenges, and many countries have taken measures to protect their origin-linked food products, countries in sub-Saharan Africa seem to lag behind. This article examines the contemporary issues surrounding the establishment of PGI in sub-Saharan Africa and describes some benefits linked to their development.

Banda, while calling for a uniform intellectual property system for Africa through the Pan-African Intellectual Property Organisation (PAIPO), notes that not much progress has been registered due to the challenges that stand in the way of establishing a Pan-African intellectual property organisation, which would have seen the harmonisation of ARIPO and OAPI systems.

The article by **Dan-Habu** questions whether the corporate entitlement to patent and design right at the expense of the individual author is justifiable and demonstrates that corporate ownership of patent and design right is more practical to business operation than any other ownership structure.

Ugwu's article analyses how international intellectual property laws of African countries can be utilised as a tool for advancing indigenous innovation and protecting traditional knowledge. The article also examines the relationship between innovation and IP, and identifies the legal principles that are best able to reconcile IP regulation with public interests like TK and indigenous invention.

Ogombe posits that courts play a critical role in enforcing patent rights and that for pharmaceutical and medical related patents in particular, the exercise of judicial authority frequently requires the balancing of two conflicting rights, that is, property rights versus human right to health.

We hope you will enjoy reading this issue of the *African Journal of Intellectual Property*.

Munani Mtetwa

PROTECTED GEOGRAPHICAL INDICATION IN SUB-SAHARAN AFRICA: ISSUES AND IMPLICATIONS

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Abstract

The emergence of Protected Geographical Indication (PGI) as an intellectual property right has brought opportunities and challenges to Sub-Saharan Africa (SSA). While many countries have taken measures to protect their origin-linked food products, countries in SSA seem to lag behind. The difficulty in doing so would not only cause the usurpation of their intellectual property rights but also preclude them from enjoying the economic and cultural benefits accruing from PGI. This article aims to examine the contemporary issues surrounding the establishment of PGI in SSA. We first briefly present the overview of PGI and then we describe some benefits linked to their development. We identified 145 potential Geographical Indications (GIs) in SSA and make a case on why they are yet to be protected. Slightly agreeing with earlier studies, we conclude that poor institutional framework coupled with inadequate capacity are the major factors hindering the development of GI in SSA. Finally, we provide policy considerations to tackle these challenges.

Introduction

The global transformation resulting from market liberalisation and development of large retail outlets have necessitated people to be conscious and protective of what they consume (Biénabe and Marie-Vivien, 2015; De Groote and Kimenju, 2008; Grote, 2009). Food safety is becoming essential to consumers due to a general income increase, which results in a change in food preference and eating habits (Bramley et al., 2003). Recently, food information, quality, and certification have become even more important than the price of food (Banerji et al., 2016; Herzfeld, Drescher, and Grebitus, 2011; Obayelu et al., 2015). For Hughes (2009) reputation and information have become the selling point of food in the contemporary world. Many people are now willing to pay more for "sustainable foods" which include environmental friendly food and origin-linked food (Balogh et al., 2016; Feldmann and Hamm, 2015; Ingenbleek, 2015; Loureiro and Umberger, 2003; Skuras and Vakrou, 2002). Therefore, the

territorial origin is now a strategic tool for food product differentiation and origin-linked food concept has spread widely (Bramley et al., 2003).

Origin-linked foods have unique characteristics which distinguish them from similar products. These characteristics could be due to the peculiarity of the geographical territory from which they originate, the indigenous knowledge of the local producers, or other qualities such as a peculiar method of production, colour or taste (Giovannucci et al., 2009; Vandecandelaere, et al., 2010). The reputation accorded to these food products can improve their market values as well as generate other non-economic benefits such as preservation of cultural heritage and environment sustainability. Due to their peculiarities and collective acceptance, origin-linked food products are often given famous names or signs necessary for recognition and differentiation. These signs or names are generally regarded as Geographical Indication (GI), and when they are certified and protected by law, they are called Protected Geographical Indication (PGI). Therefore, it is worthwhile to note that not all origin-linked products are GI and not all GIs are protected (Thevenod-Mottet, 2006). Conversely, PGI is used to protect GIs against misuse, misappropriation, and bio-piracy. When consumers are willing to pay more for GI products, the urge for usurpation becomes tempting, therefore, it becomes necessary to protect GI to enjoy what it offers (Chabrol et al., 2015).

Although the concept of GIs existed in many countries for centuries, the international effort to identify and protect them from infringement was done in the last century. Whereas many countries like India, China, Thailand and the European Union have structured their market, identified these products and gained substantially from their certifications, in Sub-Saharan Africa (SSA), this opportunity is yet to be tapped. There is a huge research gap in studies focusing on the development of GI in SSA due to a scanty scientific literature (Bramley et al., 2003; Chabrol, et al., 2015). Furthermore, the few studies conducted showed that institutional environment poses the biggest challenge for the development of GI in the region (Egelyng et al., 2016; Biénabe and Marie-Vivien, 2015; Chabrol et al., 2015). As such, the available GIs have not been given the needed attention by individual government, leaving the job of identification and registration of the products to two regional institutions, ARIPO and OAPI. The research on the development of GI starts with the identification of the origin-linked product, and many of such researches have been carried out by both the regional and national institutions. However, there is yet to be a comprehensive list of the identified potential GIs available in the region. As a result, the opportunities that PGI presents are not harnessed, and the SSA countries face the risk of their GIs being infringed by other countries or becoming generic.

Against this backdrop, this article aims to highlight the potential benefits and opportunities available for the protection of GI in SSA. It tries to provide the most up to date list of potential GIs available in SSA that are found in scientific literature. It also examines the challenges of developing PGI in SSA and suggests

policy recommendations to overcome these challenges. Our work is quite descriptive. However, it raises a number of questions about the development of PGI in SSA. We proceed as follows: first, we give the overview of GI and the benefits linked to the development of PGIs. Second, we review a synthesis of existing literature from peer-reviewed journals and scientific web pages, focusing on cases studies of PGIs in SSA. Third, we reflect on the implications of the PGIs for SSA countries and examine the related challenges. Fourth, we describe the setting up and implementation framework which should support the development of the PGIs in SSA.

An Overview of Geographical Indication (GI)

Meaning of Geographical Indication

Scholars seem not to vary in their definitions of Geographical Indication (GI), however, they have defined it under different perspectives. For instance, some scholars have associated GI as an intellectual property right (Blackwell, 2007; Hughes, 2009; de Beer, et al., 2014); others have seen it as an institutional construction (Belletti et al., 2015), while still others see it as just a sign or symbol (WIPO, 2004). Nevertheless, the underlying information is that GI is an instrument used to identify origin based products. Specifically, for Giovannucci et al., (2009) it is any "indication" that identifies origin-linked products that have peculiar attributes linked to the places where they are produced while building up a reputation over time. In a related version, Biénabe and Marie-Vivien (2015) observed it as a "name" associated with a good originating in a place, where a given quality, reputation, or other characteristics of the good is essentially attributed to its geographical origin.

In EU and other countries, a different concept has been used to promote and protect the indications/names of these types of products. The names used include "Protected Designation of Origin", "Traditional Specialties Guaranteed", "Protected Denomination of Origin", "Appellation of Origin", and "Protection of Traditional Knowledge". Although they refer to slightly different meaning, for the purpose of clarity, this article will refer to all these concepts generally as PGI, as done by Belletti et al., (2015). PGI is a framework for certifying a product which originates in the territory of a country, or a region or locality in that territory, where a given quality, reputation or other characteristic of the product is essentially attributable to its geographical origin (TRIPS, 1994; rephrased by Author).

GI products cover both agricultural and non-agricultural products. In some countries like China, India, South Korea and Colombia, it has extended to handicrafts, garments, hats, potteries, woodcarvings, ornamental flowers, traditional medicine, tobacco (Egelyng et al., 2016). Globally, some famous GIs

include *Camembert de Normandie, Parmigiano Reggiano, Basmati, Mocha, Ceylon, Champagne, Havana, Parma ham, Darjeeling tea and Rooibos* (Blackwell, 2007).

The number of GIs varies in different countries (Table 1) and obtaining the correct number of registered GIs is very difficult. This is because, in many countries, the list does not exist and in some countries where it exists, more than one of such databases are kept. For instance, in EU about four databases are maintained; DOOR for foodstuff, E BACCHUS for wine, E SPIRT DRINKS for spirits, and EUIPO database. A similar challenge was also found in the IP website of Brazil, where two databases are kept. More so, the number of registered GIs is being constantly updated as new products are registered. This has resulted in irregularities in the number of GIs reported by scholars.

Table 1: Number of Registered GIs in Selected Countries

Country	Registered GIs	Source
European Union	4 915	EUIPO, (2016)
India	282	IPIndia, (2017)
China	2 790	SAIC, (2015)
Thailand	87	DIP, (2017)
Belarus	31	National IP website
USA	206	(Mendelson and Wood, 2013)
Georgia	37	National IP website
Brazil	59	National IP website
Chile	18	Inapi, (2016)
Columbia	23	National IP website

Origin of Geographical Indication

Although the first effort to make a global recognition and certification for GI started in the late 1800s, GIs have been in existence for a longer time. The origin was traced as far back as ancient Egypt, Greece and Chinese histories, where it was used during the building of pyramids in Egypt to identify reputable bricks, and in ancient Greece it served as a sign of quality wine (Grote, 2009; Egelyng et al., 2016). However, the initial effort to espouse a common method of recognising origin-linked products was during the Paris Convention on the Protection of Intellectual Property in 1883 (Blackwell, 2007; Sharma and Kulhari, 2015; WIPO, 2004). Though GI was not a stand-alone concept from the articles of the convention, it is embedded in the "Appellation of Origin" and "Indication of Source" which were provided as means of protecting intellectual property right (Egelyng et al., 2016). An Indication of Source means any expression or sign used to indicate that a product or service originates in a country, a region or a specific place, and "Appellation of Origin" means the designation of a product by the name of the place where it derives its unique characteristics. These definitions were combined in later conferences to mean Geographical Indication.

Legislative ways of protecting Geographical Indication

There are many legislative ways of protecting origin-linked products. Since the international IP treaties could not produce a common legal means of protecting GI (Biénabe and Marie-Vivien, 2015; Giovannucci et al., 2009), different countries have adopted different means to do so. These have given rise to four known means of protecting GI in literature (Belletti et al., 2015; Henson, et al., 2011). They include protection through trademark laws, as a separate GI law *(sui generies)*, law against unfair competition, and government labelling rules and regimes.

From these four methods, two competing procedures have emerged (Blackwell, 2007):
1. collective or certification trademarks of the USA where the origin base products are protected in a similar way as any other trademark;
2. *Sui generis* legal framework of the EU, where there is a separate law for protecting geographical indication.

However, whichever method any country adopts, protecting origin-linked products have been found to have great benefits to the country (UNCTAD, 2015; WIPO, 2004). Nevertheless, this article makes the case for a "strong grounded approach" for the certification of GI (Bramley and Bienabe, 2012), preferably through the enactment of a separate GI law or dedicating a chapter of existing national IP to Geographical Indication.

Benefits of Protecting Geographical Indication

Promoting Rural Development

Protecting geographical indication can help in a rural development process through the generation of rural employment and income for farmers. For instance, in their work Vandecandelaere et al. (2010) observed that PGIs have generated increased and better quality rural employment in Europe. Belletti et al. (2015) confirmed this by stating that the valorisation of GI products can increase rural welfare and enhance the sustainable development in rural areas of any country. The reputation built around PGI products serves as goodwill which can easily be converted to extra income to local farmers, open doors for agro-tourism and eventually create valuable rural employment.

Market Creation

Another benefit of PGI is that it creates a market for goods and helps the local product to enter the international market. Where it has been certified, GI products have been shown to improve the economy and open up more markets. Bramley and Bienabe (2012) observed that GI can offer quality signalling and

assurance of the authenticity of products, help in product differentiation, market access and the capture of producer premium. For example, since its institutionalisation as GI, there has been a constant increase in the export of *Basmati* rice from India to UK, Saudi Arabia, Iran, and Kuwait which have amounted to about five billion USA dollars in 2014 alone (Biénabe and Marie-Vivien, 2015). In the EU, products like *Champagne and Parmigiano Reggiano* have become household names that depict quality and premium value. This confirms that consumers are willing to pay more for PGI products since it accords the consumers prestige, and also assures them of the safety and authenticity of the origin of the products they consume.

Preservation of Culture and Environment

PGIs help to recognise and ensure the sustainability of local intellectual heritage, culture, and the environment. Belletti et al. (2015) observed that GI is becoming a global phenomenon and many countries have adopted it as it is relevant in the preservation of cultural heritage, promotion of sustainable agricultural practices, protection and remuneration of traditional knowledge and genetic resources. The economic benefit emanating from PGI ensures that the local identity is preserved and the environmental conditions that are generating the products' uniqueness are managed effectively. This was observed in the work of Vandecandelaere et al., (2010) where they showed that a vicious circle is activated in the process of registering GI, which has the ability to ensure effective environmental management.

Prevention of Infringement and Unnecessary Cost

PGIs help to monitor and prevent infringement and usurpation (EU, 2016). Infringement occurs when other people use a GI which does not belong to them for marketing similar goods. In the event of no legal protection, real owners often face enormous cost, that includes the cost of inspection against infringement (Giovannucci et al. 2009), legal battles for usurpation (Biénabe and Marie-Vivien, 2015; Hughes 2009), and associated market failures due to free riding activities (Bramley et al., 2003). In 2014, about nine percent of EU's GI products market were infringed which summed up to a value of over four billion euros, and about 2.3 billion euros were unjustly paid by consumers who were deceived that they are buying genuine GI products (EUIPO, 2016). Many cases have been shown in literature where a huge amount of money was lost during legal tussles between countries due to misuse of GI (Biénabe and Marie-Vivien, 2015; Chabrol et al., 2015; El Benni and Reviron, 2009). Particularly, the case of South Africa and USA over the use of *Rooibos* was settled after 10 years and nearly one million USD were wasted in legal fees (El Benni and Reviron, 2009). Therefore, early certification and protection of GI products help to avoid all these issues and losses. It enables the genuine owners to enjoy the gift of nature and discourages others from interfering.

Opportunity for International Co-operation

Finally, the process of institutionalisation of PGI can help to create an international partnership. Although negotiation is still on-going for a harmonise d GI registration system around the world, through bilateral or regional trade relations, it is becoming easier to institutionalise GI thereby creating opportunities for cooperation in the process. For instance, the report from EU (2012) shows that they are willing to partner with ACP countries in developing a *sui generis* registration system. O'Connor and Company (2005) listed some of the examples of bilateral agreements concluded by the European Commission (EC) for protecting GIs in third party country. They include the EU-Australia agreement on trade in wine (1994), Canada and EU on trade in wines and spirits (2002), EC-Mexico agreements on Designations for spirited drinks (1997), Agreement between EC and South Africa on Wine and Spirits (2002). They observed that these agreements can help to build a stronger economic and political relationship between EU and participating countries.

Furthermore, the international community is bounded by the TRIPS agreement to recognised goods that have been accorded GI title in member countries. Therefore, to quicken the process of recognition, origin base products can be protected in foreign countries if local law is yet to be enacted. A good example of GI products which benefited from this process includes *Champagne and Ethiopian coffee* which have been registered and recognised in foreign countries (ARIPO, 2012). Other countries like Thailand, Brazil, and China have registered foreign GIs, thereby improving the trade relation with such countries.

Protecting Geographical Indications in sub-Saharan Africa

The Institutions

There are three institutional frameworks through which SSA countries could develop their GIs. First, it is through the international treaties and many countries in SSA are members of international treaties such as Paris Convention, the Madrid Agreement on Indication of Source, the Lisbon Agreement and the TRIPS Agreement (Table 2). Specifically, excluding South Sudan, all countries in SSA are members of the World Intellectual Property Organisation (WIPO). As a benefit of their membership, they are empowered to register their GI in another country and prohibit other countries from using an established GI from the region.

Secondly, two intellectual property rights organisations exist at the trans-regional level in SSA. The Organisation Africaine de la Propriété Intellectuelle (Africa Intellectual Property Organisation, OAPI) which covers 17 French speaking countries, is headquartered in Yaoundé, Cameroon and the African Regional Intellectual Property Organisation (ARIPO) accounts for 19 mainly Anglophone countries in its membership, is managed in Harare, Zimbabwe. In

Table 2: Membership of African Countries in Treaties Relevant to GI Protection

Name of Treaty	Total Membership	Number of African Countries
The Paris Convention	173	47
The Madrid Agreement	35	4
The Lisbon Agreement	26	6
The TRIPS Agreement	153	41

Source: ARIPO (2012)

2001, the OAPI with the support of WIPO and the French government initiated a pilot project covering the establishment of eight products as GI in four member countries (Hughes, 2009) of which three have successfully been registered by the organisation, namely, Oku White honey, Penja Pepper, and Ziama Macenta. ARIPO on the other hand signed a Stone Town Administrative Memorandum of Understanding with EU in 2012, with the commitment to working together to help build capacity and promote the practical use of GIs across Africa (ARIPO, 2015; European Commission, 2012). An effort has been made by the two sister IP organisations to harmonise their systems and mutually cooperate in the development of GI in the region. In 2017, the organisations entered a new agreement that requires that either party offers technical assistance when requested and take a common position on major IP issues affecting the member states.

Thirdly, almost all countries in SSA have a form of legal regime for GI protection either through a trademark or separate GI law. About half of the countries whose potential GIs were reported in this article have a separate national GI Act existing as a stand-alone law or a subject matter in their main IP law. Furthermore, the member countries of ARIPO and OAPI can protect their GI under the framework of the Lusaka and Bangui Agreements respectively. Although subscribing to the membership of the regional IP institution is necessary for the development of GI, it is however not sufficient. The study of Uluko, Oyewunmi and Mandewo (2012) opined that by a mere revision of the trademark regimes or adoption of a simplified *sui generis* system, many potential GIs in SSA can be protected at national level. While having a separate national GI law will reduce the huge burden on the trans-regional GI institutions, it will present a great opportunity for a tailored and grassroots oriented approach.

The GIs

There are many origin-linked products in SSA which can generate much economic benefit if protected and animated. From Rooibos tea in South Africa to Sissili shea butter in Burkina Faso, many products in the region have built reputation globally but few have been registered. The list of potential GIs in SSA is shown in Table 3. The GIs were collated from scientific literature and IP websites. A total of 145 potential GIs were found. The products include

foodstuff, handicraft, and traditional specialties but excluding wines and spirits. It also includes the three products that were registered by OAPI and some other products that were registered in foreign countries like Rooibos tea. It is important to assert that the collection was done within the limit of the authors, and there would be many more potential GIs which were not reported. The compilation was done from several scientific literatures. The final column shows if there is yet to be a dedicated national GI bill in the countries listed. This information was obtained from the WIPO website as at February 2017.

Table 3: A List of 145 Potential Geographical Indication Products in SSA

Country	Potential/Registered GI	National GI Act
Botswana**	*Ghanzi Beef, Ngami/Nhabe Basket*	Subject Matter in the Industrial Property Act, 2010
Benin*	*Savalou gari, shea butter*	No
Burkina Faso*	*Massina Kwite butter, Faso Shea butter, Souflou green beans, Bobo for plank masks*	No
Cameroon*	*Oku white honey, Penja pepper*	No
Chad*	*High-grade cotton*	Subject Matter in Law No 005 / PR /2003
Congo*	*Kivu, Ituri for coffee*	Subject Matter in Decree No. 2001-238
Ethiopia	*Harenna wild coffee, Wenchi volcanic honey, Wukro honey, Forest Pepper*	No
Gabon*	*Sweet potato, Okoumé Timber*	No
Ghana**	*Ghana cocoa, Kente cloth*	Geographical Indication Act, 2003
Guinea*	*Mafeya pineapple, banana Conakry, chili de Mamou, Diama coffee, Ziama-Macenta robusta coffee, Boké palm oil*	No
Cote d'lvoire*	*Korhogo fabrics, Man Mountain rice, Atcheke of Grand Lahou*	No
Kenya**	*Kenya (Arabica) Coffee, Cut Flowers, Kiondo (sisal handbags), Kisii Soapstone Ornaments, Wamunyu handicrafts, Kakamega Wild silk, Kenya tea, Mwinigi honey, Mt. Kenya coffee, Gathuthi tea, Kisii tea, Kericho tea, Kangeta, Miraa, Meru potato, Kikuyu grass, Mombasa mango, Machakos mango, Asembo mango, Muranga bananas, Kisii bananas, Molo lamb, Kitengela ostrich meat,*	Subject Matter in Protection of Traditional Knowledge and Cultural Expression Act, 2016

	Omena fish, Mursik milk, Keringeti mineral water, Tsavonite, Magadi soda, Kenyan kiondo, Naivasha wine, Kakamega Papaya, Kakamega omukombera, Tilapia fish from Lake Victoria fish, Lake Turkana fish, Akamba carvings, Maasai attire, beads, Machakos Honey, Bixa, batiks, Gum Arabic, paw-paw wine, Ukambani honey, Ngoe mangoes and Khat-(Miraa)	
Madagascar	*Mananara vanilla, Pink rice from Amparafaravola Imraguen*	No
Malawi	*Mzuzu coffee, fish (Chambo fish), peanuts, tobacco, macademia nuts, chillies, Malawi tea,*	No
Mali*	*Dogon Shallot*	Subject Matter in Industrial Property No.87 18/AN-RM
Mauritania*	*Imraguen women's mullet bottarga*	No
Mauritius	*Chilis, pickles, beeswax, Petit piment confit, Aigre-doux de limons, Piment de manges, Piment de limons, Piment de papayes, Achard Bilimbi longue, Achard de carambole, Achard de limons, Piment de Tamarin, Pâte de piment rouge, Pâte de piment vert, Achard de fruits de Cythère, Demerara Sugar, Baie Topaz Red Beans, Piment Rodrigues, Bois Cherie Tea, Tai So Litchi, Cut Flowers, Rodrigues Honey, Rhum St Aubin, Café de Chamarel*	Geographical Indication Act, 2002
Mozambique**	*white prawn, tete goat meat*	Subject Matter in Industrial Property Code 2015
Namibia**	*Kalahari Melon Seed Oil, Karakul fur*	No
Niger*	*Galmi Purple Onion*	No
Nigeria	*Yam, Kola nut*	GI for Wine Regulation 2005
Rwanda**	*Rwanda coffee (Red Bourbon Arabica)*	Subject Matter in IP law No. 31/2009
Senegal*	*yêtt de Joal, Fruits from Lower-Casamance*	No
South Africa	*Rooibos, Honeybush tea, Karoo Lamb, Camdeboo Mohair, Klein Karro Ostrich, Aloe Verox, Idumbe, Hoodia, Bhugu, several wines*	GI for Liquor and Methylated Regulations, 2004

Tanzania	*Konyagi (alcohol), Kilimanjaro coffee, M'Bigoiu for sculptures, Zanzibar Cloves, high value vegetables, cut flowers, Kyela Rice, Kilimanjaro Sugar (TPC), Kilimanjaro Aloe Vera, Tanzanian Peaberry*	No
Uganda**	*Waragi (alcohol), Barkcloth (Ladies bag)*	Geographical Indication Act, 2013
Zimbabwe**	*Tobacco and Chipinge coffee*	Geographical Indication Act, 2001
**Member of OAPI, **Member of ARIPO*		

The Market

Although, there is yet to be a comprehensive study on public perception and willingness to pay premium prices for PGI in SSA, related studies conducted in SSA countries on GI tend to suggest that the local people are willing to pay more for origin-linked products (de Beer et al., 2014; Chabrol et al., 2015). For instance, in Mali, the preference for the highly priced shallots over onions is because it serves as a cultural heritage and identity. Secondly, urban dwellers in SSA have been found to purchases foods coming from their state of origin in order to reconnect to their roots and traditions. Thirdly, the study of Uluko et al. (2012) showed that Malawian consumers are not only influenced by price but also the GI associated with a product. This is in line with the concept of solidarity identified by Belletti et al. (2011) and Reviron, et al. (2009). GI helps to form networks which encourage cooperation and solidarity among people of common origin.

Furthermore, the evidence from the registered GIs in SSA shows that when legally certified and effectively marketed, the GI in SSA have the capacity to increase sales, achieve a higher selling price, and access export market easily. The case study of the first three GI products to be registered by OAPI was done by Chabrol et al. (2015). They showed that for Oku white honey of Cameroon, the selling price increased 100 percent in five years from €40,000 to €80,000. The reason of this is that the uniqueness of the honey became recognised by the inhabitants of the territory where it is produced. Unlike previously where it was considered defective by the local people due to its white colour, the revalorisation through GI registration improved its market value. More so, they reported that the demand for the product is growing in large cities. This is similar to the case of Penja pepper where both production and price increased by 50 percent, and the products are currently being exported. Finally, for Ziama Macenta coffee of Guinea, the GI development equally opened the international market for the product.

With the availability of a great number of potential GI, the legal regimes, and positive impact studies, it becomes a thing of wonder why many countries

in SSA still lag behind in the development of their GIs. The following section presents the factors hindering the successful implementation of GI in the region.

Challenges in Developing GI in sub-Saharan Africa

Institutional Challenge

While many countries in SSA have a regime for GI protection, as shown in Table 3, the literature shows that in some countries in SSA the available trademark regime is inadequate in protecting GIs (Hirko, 2014; Uluko et al., 2012). Kenya, for instance, has more than 45 potential GIs and a Trademark Act, but the delay in passing the GI bill was the major factor preventing the registration of their GIs. A similar reason was given for Malawi by Uluko, et al. (2012) where it was observed that the available Trademark Act needs to be revised to meet current expectations.

Although having ratified the TRIPs agreement, many countries in SSA are still fixed in their bid to choose between the USA trademark certification regime or the EU separate sui generis system for GI protection. The lack of agreement on method tends to compromise the regional effort for enforcing a common IP rights regime. The mutual cooperation between ARIPO and OAPI in achieving a unified legal framework and method for identifying GI is therefore very vital to solving this issue. Secondly, some countries have shown an effort to enact a separate law for GI protection; however, in most cases the process has been delayed. For instance, Egelyng et al. (2016) showed the case of the Kenyan GI bill which was later enacted after almost 10 years. Thirdly, in countries where the bill is available, enforcement of such laws is poor. Zimbabwe crafted the GI Act in 2002 but only to make it operational in 2016 (Nyakotyo, 2013; ZIPTA, 2016). This represents a delay of more than a decade and a loss of opportunities. Having seen that the enactment of separate GI laws has helped to revalorise GI products in India, China, and Thailand, it is opined that SSA nations should strive to urgently amend their IP laws to allow a seamless registration process.

Resource Challenge

The registration and protection of GI is an investment that requires resources (African Union - European Union Workshop, 2011; Blakeney, 2009). In the case of protection, adequate resources in the form of finance in different jurisdictions are a precondition for the effective management of the GI system (Blakeney and Coulet, 2011). However, a majority of countries in SSA are low-income countries, hence a GI development system can put pressure on the already meagre government revenue.

Vandecandelaere et al. (2010) emphasised the need for skilled and experienced personnel from identification, qualification, remuneration to reproduction of potential GI. However, the skills to identify the unique characteristics

of products is a challenge in SSA and the capacity to monitor infringement and enforcement of IP rights is also poorly developed (Petit and Ilbert, 2015; Mengistie, et al, 2012; Musungu et al., 2008). This perhaps stems from the fact that GI valorisation is a relatively new concept in the region, hence there is a general lack of experience which is a very important factor if success is to be realised. In this vein, it is important to point out that though legal institutions exist for most countries, PGI is a recent phenomenon that needs awareness (O'Connor and Company, 2005). Therefore, it is important that the public is enlightened about the significance and potential of GI products.

Finally, protection of GI requires knowledge about supply and value chains (Musungu et al., 2008). The majority of cases of imitation and bio-piracy as well as misuse of GI names are a result of unclear and inadequate knowledge of what happens when a product leaves the farm gate. A number of studies found that the majority of producers are not aware of the destination of their products, let alone port of export and retail prices (John, et al., 2016). These studies suggest that most of the rural stakeholders who are supposed to be involved in the registration and management of GI products have limited knowledge of value chain and activities which is a challenge for the development of GIs.

Territorial Challenge

GI is a collective mark that protects origin-linked products from a particular delimited territory (Vandecandelaere et al., 2010). It, therefore, requires collaboration and compliance among members of the community, especially the producer's group in which case, well-organised producer groups are a necessary condition for GI valorisation (Hirko, 2014). However, such producer groups are quite complicated in SSA countries. In most SSA countries, studies showed that many producer organisations collapsed after the 1990s structural reforms and efforts to revitalise such groups require not only a big push but compliance with International Cooperative Alliance principles.

Furthermore, the existing producer groups are faced with a myriad of challenges that could hinder them from participating in GI development. GI products are mostly products from marginalised or remote areas, and the local organisation may not be aware of the economic opportunities that are hidden in their foodstuff or traditional knowledge. Furthermore, the disconnection between the urban and rural areas where these products are found, the poor rural infrastructure, low education, and the existence of rural stakeholders with divergent interests can pose challenges for GI elaboration in rural territories in SSA.

Tomspon, et al. (2009) studied the challenges and opportunities for strengthening farmers organisations in Africa. Drawing lessons from rural areas in Ethiopia, Malawi, and Kenya, they observed various bottlenecks that must be overcome for farmer producer groups to be able to engage in collective identification of GI

products. They stated that first and foremost, producers' groups must operate in a business-like fashion. With a profit-making motive, producer organisation can be inspired to work towards GI development. Secondly, there is a need for manpower development through training and extension. Thirdly, the high entry requirement should be made as easy as possible to enable the majority of farmers to participate. Finally, the producers' groups need funding to carry out the GI establishment process.

Generic Challenge

The international GI recognition is often demonstrated to be difficult (Petit and Ilbert, 2015). Some names of products in African countries have become so generic that protecting them in international markets is often challenging. In that case, it may be difficult to prove in certain cases that the product requires specific right in the GI system. For example, names such as Safari and Karoo used in SSA were rejected to be accorded GI recognition in the United States on the basis that they are too generic (Sibanda, 2016). Similarly, the case study of Ethiopia and Starbuck Coffee War in protecting its coffees through a trademark in the United States shows that it is often challenging for countries seeking market access and protection to gain easy recognition (WIPO, 2004). A well-developed national database system with a clear demonstration of the product unique characteristics is necessary.

Policy Measures to Overcome the Challenges

The study so far has demonstrated that PGI is essential for development in SSA, however, the above challenges cannot be ignored as far as successful protection and management of a stronger GI system are concerned. It is imperative to map the way forward for most countries in the sub-Saharan Africa who are struggling to tap into the benefits of GI products. The implementation framework, therefore, includes some elements:

i. Countries who are yet to do so should craft a country specific GI legislation. Whilst trademarks and other certification have been shown to offer some protection to GI products, it is clear that if countries are to gain from the reputation of their products, strong statutory provision, and management of a separate GI regime is needed.
ii. There is a need for national governments to have strong investment commitments towards GI development. Whilst donor support is important in technical assistance, public investments are very essential for infrastructure and educational development particularly in GI territory and in rural areas as a whole. National governments should seek to equip key players in specific GI products with essential knowledge such as product characterisations and the complete value chain identification.
iii. Because GIs are collective marks, successful PGIs have been shown to have

strong producer groups. While a majority of SSA countries faced a collapse of the cooperative sector after the liberalisation era (Nyangito, 2002), the need to encourage the creation of producer groups for GI products and at the same time recognising the principles of cooperation is important.

iv. It can be asserted that developing a GI at the regional level is a long process, however, having a comprehensive database of GI at the national and trans-regional level is a good step. More so, national GI registration procedure should be made easier and cheaper. While we have made the initial effort of compiling the names of available GI for SSA from the scientific literature, individual countries should map out means of developing such a register. Consultancy with relevant institutions, researchers, and property rights legal experts can be helpful.

v. It is important that consumers recognise the value of a GI, which in turn means that a marketing strategy has to be designed. Stronger state support can be helpful in setting up the GI also for this aspect (Bramley and Bienabe, (2012), but often it is common to link the success of GIs with a long-standing popular product of which marketing was further developed by strong private partners (Giovannucci et al., 2009). Marketing then represents a huge part of a GI success (Sharma and Kulhari, 2015).

Conclusion

PGI is relatively new in SSA. While many countries have taken measures to protect their GI, countries in SSA seems to lag behind. The negligence in doing so would not only cause usurpation of their IP rights but also the inability to enjoy the huge economic and cultural benefits accruing from PGI. The importance, opportunities, and challenges faced by SSA countries in establishing PGI were examined. There is limited scientific literature on this area of research in the region. Nevertheless, the establishment of a functional PGI system will help SSA countries to discourage free riding of their GIs. When GIs are legally protected by the national or regional institution, it helps to control the market failures arising from usurpation; it improves rural development; ensures environmental sustainability and leads to general economic and social development.

However, certain challenges need attention as far as the success of protecting products of origin is concerned. These challenges were categorised under institutional, resource, territorial and generic challenges. We agreed slightly with scholars who opined that the inability of SSA countries to develop their GI is mainly due to a poor institutional environment. We assert that almost all countries in the region have at least a legal regime for GI protection, and many are adopting the sui generis system, however, stakeholders lack proper experience and skill for GI development.

Achieving meaningful results in protecting GI by national government requires not only technical assistance from other countries or total dependence on

ARIPO and OAPI but a well-crafted legal framework which is easy and cheap for the people. A database of potential and registered GI needs to be kept by the individual government and transnational IP institutions. More research is called for especially on the cost-benefit analysis of the establishment of PGI in SSA, and the willingness of stakeholders to participate or pay premium prices for PGIs.

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CHALLENGES FOR THE HARMONISATION OF AFRICA'S INTELLECTUAL PROPERTY SYSTEMS THROUGH THE PAN-AFRICAN INTELLECTUAL PROPERTY ORGANISATION (PAIPO)

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Abstract

Despite a decade long talk on the need for a uniform intellectual property (IP) system for Africa through the Pan-African Intellectual Property Organisation (PAIPO), not much progress has been registered to date. The once colourful dream of bringing under one roof the regional IP organisations in the name of African Regional Intellectual Property Organisation (ARIPO) and African Intellectual Property Organisation (OAPI) seems to have faded with time. Of late, the regional organisations have proceeded to sign harmonisation agreements, between themselves even though such initiatives still lack continental inclusiveness. This article explores, through a review of existing literature, the challenges that have been standing, and continue to stand in the way of establishing a Pan African intellectual property organisation, which would have seen the harmonisation of ARIPO and OAPI systems. The article highlights some key existing differences within the two organisations that would possibly hinder harmonisation of the two organs through the PAIPO model of a merger. The article also brings to light how PAIPO may not be in a position to serve the IP needs of Africa as a continent if it took on board ARIPO and OAPI in their current mandate. Throughout the discussion, the article makes certain recommendations of how those challenges could be resolved in order to enable the Pan African Intellectual Property Organisation to realise its objectives.

Introduction

Intellectual property (IP) in its broadest sense refers to the creations of the human mind (Idris, 2003). The necessity of protecting IP rights within the international, regional and national frameworks has been acknowledged all over the world. IP systems contribute to the self sustaining development of local economies and are therefore part of the essential infrastructure of African countries in that, under proper IP protection, local industry would confidently promote innovation and develop original brands, and foreign entities would increase investment and research and development activities. Presently in Africa, two major regional organisations dealing with the protection of IP

exist: the Africa Regional Intellectual Property Organisation (ARIPO) and the Organisation Africaine de la Propriété Intellectuelle (OAPI).

Both OAPI and ARIPO were established at the time most African countries had just gained independence but critics have argued that the provisions establishing these two regional organisations do not adequately reflect the true African values. Kongolo (2000) observed that the systems set forth in the organisations referred to above, have not yet been able to contribute in a positive and effective manner to the development process of their member states. The two organisations therefore still have a long way to go to be considered as effective tools for the development of their member states.

It is also surprising to note that despite IP being an economically empowering force, not all African countries are members of ARIPO or OAPI. The combined membership of ARIPO and OAPI currently stands at 36 countries, yet Africa has a total of 54 countries. The remaining 18 countries, mainly in North Africa, are not represented by any regional institution and have each relied on their national IP arrangements to address IP matters (Idris, 2003). Notably also, most IP legislation remains outdated and does not reflect current trends in global IP regulation. These are among several shortfalls mentioned in relation to IP issues affecting Africa that gave rise to the idea of the establishment of a Pan African IP system.

The Idea of a Unified Intellectual Property System for Africa

The preferred scenario for IP protection for Africa has been to establish an organ unifying Africa's IP systems to ensure that IP serves the needs of each of the African countries based on its developmental stage, and the nuances of its socio-economic and cultural circumstances (Kongolo, 2000). The widely agreed upon solution to these discrepancies has been the necessity of setting up a new African organisation that should adapt to the realities and needs of Africa as opposed to IP laws that appear to be mere repositories of western-based IP needs. These sentiments prompted the push to establish the Pan African Intellectual Property Organisation (PAIPO). The idea for PAIPO is described in the African Union Concept Paper which emerged from an Extra-ordinary conference of the African Ministers of Council on Science and Technology that took place in November 2006 (Gerhardsen, 2007).

In support of the setting up of a new IP structure for Africa, the PAIPO Concept Paper calls for the development of appropriate legal and institutional infrastructures to support innovation and enforcement of IP rights, to ensure that IP serves as an incentive for investment and research in Africa. The PAIPO idea has however not gone without criticism. For instance, as Karjiker (2012) reports, the PAIPO initiative has been condemned for being biased towards foreign IP rights holders by seeking to adopt "first-world" standards of

protection; failure to address the needs of Least Developed Countries (LDCs) in Africa and lack of consultation and transparency in the process leading up to the production (and potential adoption) of the draft PAIPO statute. The lack of consultation criticism is collaborated by ARIPO and OAPI in their 2014 joint communiqué on PAIPO (Ncube, 2014).

Nevertheless, it is strongly felt that a unified IP system would be beneficial for Africa as a whole. Among the positive aspects of such an undertaking, Africa would get rid of the shortfall of varied policy and legal frameworks amongst the states. The different policies and legal frameworks are difficult to implement, for example where the IP owner is from a different country and is seeking protection or enforcement of his/her rights in another country. Since IP laws are territorial in nature, it is difficult to enforce one's rights in countries where for instance, a particular IP law does not exist (Shaheed, 2000).

Secondly, as Kongolo (2000) notes, the establishment of an Africa-wide IP structure would sharpen the visibility of IP issues as they relate to economic development, which seems not to be highlighted in some countries in the present scenario. This will add impetus to the leaders' political will and commitment to inventiveness and innovation, thus emphasising the significance of political leadership in such a strategic field of development.

In addition, an opportunity arising from a unified IP system is with regard to trade within and beyond the continent. If IP laws had been made uniform in all states of Africa, there would have been created a conducive environment for trading within as well as outside the continent. For instance, effective IP rights (IPRs) enforcement measures would not only attract Foreign Direct Investment (FDI) but would also enable domestic IP owners to recoup their investments in research and development (R&D) since the export and import of counterfeit products would be minimised through a uniform and effective border measure system. Shaheed (2000) notes that counterfeiting and piracy create conflicts with a developing country's major trade partners and that their control is essential for creating the necessary environment in high technology enterprises. An integrated approach to the problem is important.

Furthermore, an opportunity from a unified IP system would become evident with regard to IP developments at the international level. Africa would be in a position to speak with one voice on matters of interest and benefit to the entire continent. Already, recent developments at various international forums have necessitated for Africa to speak with one voice. One notable example relates to the protection of Genetic Resources, Traditional Knowledge and Expressions of Folklore, in which Africa is heavily endowed. Such cooperation will be of use in future multilateral negotiations because it will enable the continent to form a lobby block on issues that affect them the most, such as the present demand for benefit sharing for the use of traditional knowledge and genetic resources.

Notably also, with unified policy, greater IP awareness, training and capacity building would be forged continent-wide. Terroir (2016) notes that some countries in Africa have made some strides with regards IP awareness, training and capacity building, while others still lag behind. A unified IP system would ensure that efforts for IP awareness training and capacity building are spread across the continent, providing an atmosphere where those countries lagging behind are given the opportunity to learn from the model countries, thereby enabling such countries to take positive strides in the development of their own awareness, training and capacity building programmes.

One other opportunity that would arise relates to the issue of funding and innovation of IP. As Terroir (2016) notes, studies have shown that some countries within Africa are struggling to get funding for the development of IP and innovations, and so a harmonised IP system would be better positioned to push for funding for IP in all the member states. This could be implementable in several ways, for instance where the IP organ sets for its member states, minimum requirements regarding funding for IP. Thus with a unified IP system, the significant variations that exist in respect of IP matters among the African countries would be reduced and possibly eliminated all together with time. Africa would for once have an opportunity to influence and play an active role in its own economic development.

It is thus not surprising that the two regional IP organs have been and continue to explore ways of collaborating on IP matters. Evidently, the two organs signed memoranda of understanding, first in 1996, which was followed by another in 2005. As recent as February, 2017, the two organisations also signed another agreement aimed at harmonisation of their systems; exchange of documentation and technical information, mutually cooperating in the development of training and joint capacity building in user awareness (Williams, 2017). This underscores the dire need for Africa to have a unified IP system, which unfortunately is refusing to take off through the PAIPO idea. The measures being taken by ARIPO and OAPI towards harmonisation amidst the talk of a Pan-African IP organisation may well be interpreted as an indicator of the amount of scepticism the two organisations have as regards the PAIPO idea being implemented anytime soon, probably attributable to lack of consultations at the inception.

In spite of the aforementioned, some analysts have expressed hope that the PAIPO dream, if properly worked on, could turn into an effective reality of harmonising the operations of ARIPO and OAPI. From the outset, those framing the idea of a Pan African Intellectual Property Organisation decided not to leave aside the two regional IP organisations in their quest for a uniform IP system for Africa, appreciative of the role the two organisations are already playing.

The On-Going Process for the Realisation of the PAIPO Dream

Although PAIPO appears to be a better option for bringing about a unified IP system for Africa compared to the current set up, certain hurdles still exist that make it impossible for the PAIPO idea to be realised. The implementation of PAIPO has not been an easy task. For instance, in December, 2008, a blueprint for the proposed PAIPO was sent back to the drawing board by the steering committee of the African Ministerial Council for Science and Technology (AMCOST) bureau, dashing the hopes that it could be adopted by presidents the following January. This was probably for the reason that African countries, including members of the current regional IP organs, have within themselves different interests and priorities in the area of IP. The Abuja meeting noted that the blue print design, despite being drawn in consultation with relevant stakeholders, including ARIPO and OAPI, was too bureaucratic as it had proposed for the establishment of a new ministerial forum to be known as African Ministerial Council for Intellectual Property (Nordling, 2008).

From the very onset, although hope was expressed that the final plan for PAIPO would be ready for submission to the Heads of State summit during 2009, the Abuja meeting was quick to acknowledge that coming up with an appropriate design for PAIPO was without doubt a difficult and time consuming task probably because of the challenge in merging the operations of two regional organisations with different operation systems.

Further, while the 20th Ordinary Session of the African Union in January 2013 decided to establish PAIPO and requested for a meeting of all stakeholders in the implementation by May of the same year, surprisingly the PAIPO Stakeholder meeting was not part of the 21st Ordinary Session that year. In 2014, ARIPO and OAPI had to issue a joint statement, expressing their views on PAIPO, and requesting their involvement in the consultative process regarding the PAIPO proposal. Just as happened in May 2013, the 2015 AU Summit does not minute any PAIPO related discussion (Ncube, 2016).

The first 10-year plan of the Agenda 2063 covering the years 2014-2023 however mentions something on PAIPO to the effect that the PAIPO Draft statute would be reviewed by the Specialised Technical Committee on Justice and Legal Affairs and thereafter be approved by the Summit in 2016; consultations with Tunisia (host country) would be undertaken in 2017; the adoption of the Implementation Action Plan by the Assembly ought to be achieved in 2017; PAIPO would then commence its activities in 2018; and should be fully functional by 2023 (Ncube, 2016). Whether the Agenda 2063 first 10-year plan is to register any tangible developments towards the establishment of PAIPO or whether it will be another long episode of pushing the document from one committee to the next remains to be seen.

Existing Fears Surrounding the Idea of the 'Marriage' of ARIPO and OAPI in the Name of PAIPO

Some scholars have argued that instead of Africa pushing the PAIPO idea, it is the WIPO secretariat that is in the forefront driving the AU secretariat towards the creation of PAIPO, with the goal of extending the OAPI/ARIPO model - controlled by WIPO - to the entire African continent (Gerhardsen, 2007). Resultantly, the PAIPO arrangement would considerably reduce the capacity of important non-OAPI/ARIPO members such as South Africa, Egypt and Algeria to take independent positions on IP at the international level.

Some quarters have also observed that for as long as the new IP organ adopts the systems of OAPI and ARIPO in their current form, the objective of having a unified IP system for Africa would still not be achieved. One such observer, Waruru (2016) argues that the two regional IP bodies in Africa, do not, strictly speaking, provide an opportunity for their member states to fully exercise their patent rights and counter IP "mercantilism," nor do they provide links to free trade and bilateral investment agreements with external partners. On the same note, there is an observation that whereas there are IP offices in all the member states of ARIPO, OAPI provides IP services for its member states but the degree of sovereignty of the member states on IP matters differs greatly between the two organisations. While ARIPO maintains the national industrial property offices as independent entities, OAPI on the other hand serves as the national industrial property service for its member states. Furthermore, even though the filing procedures in both organisations are similar, under ARIPO a member state might give notice that an application properly filed with the regional body will not apply to her. This is unlike the provision in OAPI, which only subjects application of the regional laws to the laws of any given member state. Thus, this difference in the degree of sovereignty raises the fear that there would be a challenge in bringing the two organisations under PAIPO since the respective member states are already used to their different approaches.

The protocols that govern the operations of the two organisations also present a sharp contrast. While ARIPO has separate protocols for Marks and the other for Patents, Industrial Designs and Utility Models, and provides that member states are free to accede to one or both, OAPI on the other hand has only one agreement (the Bangui Agreement) which encompasses all areas of IP protection and accession to the agreement automatically means accession to all its contents. This, in the event of a marriage of the two through PAIPO would be a challenge since some member states are used to having the freedom of choice of the protocol they deem most suitable to them. This might especially be the case with ARIPO member states, as some have already shown a reluctance to adhere to other forms of protection within the organisation (Kongolo, 2007).

Conclusion

The implementation of the PAIPO statute continues to face resistance in every way, a decade after its proposal for establishment. Every effort to implement the statute against all odds seems not to work. Over a decade since the inception of the PAIPO idea the PAIPO document keeps on being moved from one committee to the next. The initial irregularity was that at the inception of the idea, there was not much stakeholder involvement and consultations. This has resulted in the idea getting a lot of criticism and lacking the support of some relevant stakeholders at a time when such support was needed most, a situation which has almost stalled the process.

Noticeably also, the place of the two existing regional organisations in the context of a unified IP system seemed not to have been given much attention and thought. The PAIPO Concept Paper does not adequately address how the existing differences between the regional organisations would be handled in the context of a unified system. Resultantly, this lack of certainty has raised fears in some quarters. Nevertheless, with proper re-designing and implementation, the PAIPO model would be a sure way for the much needed unified IP system for Africa.

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JUSTIFYING EMPLOYER OWNERSHIP OF PATENT AND DESIGN RIGHTS IN NIGERIA AND KENYA

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Abstract

The typical legal environment in relation to patent and industrial design rights ownership in Nigeria and Kenya is such that the employer owns the right and can undoubtedly have these rights asserted by the courts against the creators and inventors. This appears inconsistent with Locke's philosophical ideas that have been acknowledged by various legal scholars as an authoritative justification for intellectual property (IP) right. If Locke's philosophy underpins IP law, how might we explain the rights that accrue to the employer? It is definitely worth taking a step back and examining the rationale behind the detachment of ownership rights from the creator. The question this article seeks to answer is if the corporate entitlement to patent and design right at the expense of the individual author is justifiable. By exploring a range of alternative options, this article will demonstrate that corporate ownership of patent and design right is more practical to business operation than any other ownership structure.

Introduction

An examination of the diverse African and foreign jurisdictional approach to ownership confirms that most employees do not own the right in the patent and designs. In Nigeria, the Patents and Designs Act (PDA) provides for all inventions and designs created in the course of employment or in the execution of a contract for the performance of a specified type of work to vest in the employer (s2 (4) and 14(4) Patent and Design Act, 1970. However, it is worth noting that the right of the employer to be granted the patent and design is not absolute. The law provides for "fair remuneration" to be awarded to an employee that is not required, by the nature of his employment, to exercise any inventive activity but has made an invention utilising facilities or data provided by his employer (s2 (4)(a)(i) PDA). Additionally, it also provides for the award of "fair remuneration" where the invention is considered to be "exceptionally important" (s2 (4)(a)(ii) PDA). Unfortunately, the PDA does not provide for what is to be regarded as "exceptionally important" and the tern is thereby subject to varying interpretation (Nwogu, 2015). While most inventors would be inclined to consider their work as "exceptionally important", employers may agree otherwise.

On another hand, the law in Kenya provides that the invention made in the execution of an employment contract with the use of the employer's resources, belongs to the employer (See s16 (3) Industrial Property Act, 2001), but where the invention is made without any relation to an employment contract and without the use of the employer's resources, the right to exploit the invention solely belongs to the employee (See s16 (2) IPA). Where there is no express contract and the employer and employee equally contributed to the resources used increating the invention, the law provides for "joint ownership", with the employer having exclusive right of exploitation and the employee, the right to fixed remuneration. Despite the fact that Kenyan law makes the employer's ownership right subject to contract while Nigerian law does not, it has been suggested that the laws have similar effects, as inequality in bargaining power leaves employees open to exploitation as the employee is unable to exert any control over the terms and might be unable to secure any employment in the areas of expertise if such agreements are not signed (Bartow, 1996).

Furthermore, other African jurisdictions such as Swaziland, Lesotho, Mozambique, Malawi, Tanzania, Uganda and Ethiopia maintain similar approaches to this area of law where ownership typically rests in companies that employ the inventors and designers (Wekundah, 2012). This ownership structure is also analogous to western jurisdiction; for instance, in United Kingdom (s.215(1) and (30) CDPA) and Australia (s13(1) of the Design Act 2003), the law recognises the employer to be the owner of the patent and design right if the work was made in the course of employment.

These laws appear inconsistent with the Lockean theory, a philosophical idea that has been acknowledged by various legal scholars as an authoritative justification for intellectual property rights (Becker, 1977; Grunebaum, 1987). The Lockean theory asserts that property rights exist after a person labours upon resources that are "held in common" or unknown; thus, the labourer acquires a natural property right from the resulting product of his labour (Mgbeoji, 2012). However, it is evident that not all labour results in the ownership of a property right. The question thus becomes, why should the employer own the fruits of the employee's unique talent, skills and insight? Should we defend a system that allows the risk-taking corporation to reap the rewards of the hard-working individual? Like Mgbeoji asks, "what effort of theirs was applied to the thing to create the property? Is their shareholding to be construed as effort or labour?"

Criticisms have arisen against this system, mostly on the basis that it is unfair and that it damages the incentive to be creative. It is worth specifically addressing these concerns.

Fairness

Existing body of literature challenging the fairness of this legal structure consider it unfair to the employees and exceptionally favourable to the employers (Bartow, 1996; Riley, 1994). According to Riley, this system of

employer ownership "drains a person's productivity in the same manner that communist countries stifled their workers' will to produce". Riley further asserts that "allowing businesses to exploit their employees by assuming rights over their inventions, is morally and ethically wrong". This is based on the premise that compared to the employer; the employee contributes substantial investment to the design. Therefore, the argument goes, and the employee deserves a greater reward. According to Bartow:

> It is unjust that an employer reaps all of the rewards [...] as the "payoff' for the resources it devotes to an invention, but an employee-inventor who has also made a substantial investment in the inventive process-potentially at a level of personal sacrifice disproportionately greater than any financial or "opportunity cost" risk assumed by the employer is usually precluded [...] from profitting from the fruits of his or her labour in a manner commensurate with, or even proportional to, the value and utility of [the design or invention]…

Several researches go as far as recognising the personality element in an intellectual property and advocating for an employee ownership, arguing that an employee's creation is an extension of his personality and consequently in some sense his (Cherensky, 1993; Gordon, 1993; Hughes, 1998). The argument further goes that the employee might devote themselves to investing copious amount of time, energy, intellect, training and constant thought to the creation of innovative and complex ideas, thus, the creative process becomes bound up in their personhood. The employer should therefore retain significant interest in the invention. Cherensky(1993) describes the creative process by relaying the comments of an innovator:

> [...]Innovation is an emotional experience [...]. The desire to innovate comes partly from the genes; you're born with it. It also comes from your early life, your education, the kind of encouragement you got to be creative and original. Innovative people come in all shapes and sizes and in all personality types. Some people are happiest when they're wrestling with a problem; I'm one of those. Others go into a green funk. They're miserable and depressed until they have the answer. But you can't have a good technologist who's not emotionally involved in the work. You can't have a good technologist who doesn't wake up in the middle of the night searching for answers. You can't have a good technologist who doesn't come into the lab eager to see the results of last night's experiment.

While these are reasonable arguments, it is impossible to note that, to a very large extent, it undervalues the unique and important role the employer plays in the innovation process. Most R&D projects require enormous expenditure. Drawing on various quantitative studies, and his independent research, Scherer indicated that companies require 'expensive marketing and roll-out campaigns'. Furthermore, the corporation has to continually invest resources on 'incremental improvement and process innovation' (Silverman, 1989). By undervaluing the role of the corporation, we make the mistake of disregarding the significant role of business strategy in fostering innovation and generating increased consumption.

Creativity Incentive

The other major criticism against this legal structure is that it dampens the incentive to create and fails to encourage innovation. Intellectual property rights are believed to be the rewards given to creative persons, with the intention of motivating them to be more creative. This theory is grounded on four significant premises (Cherensky, 1993). The first premise is that innovation requires labour. Secondly, the labour required is rather unpleasant, or less pleasurable than leisure. As a result, an innovator will not merely choose to innovate for the fun or love of it; they would require an external inducement. Thirdly, innovation (newer designs) generally improves the welfare of the society. Therefore, it is important for society to create and offer incentives for innovators who suffer the unpleasantness of labour. In the words of Abraham Lincoln, intellectual property right adds "the fuel of interest to the fire of genius" (Lincoln, 1859).

While proponents of this school of thought argue that the "corporate usurpation of inventive bounty" (Bartow, 1996) might discourage the employee from making his design public and capitalising on his idea, it is however entirely obvious that a designer could be motivated in his creative effort by something other than an ownership right. Employees may prefer short-term benefits such as income, bonuses, and perks over ownership right. Also, as business writer Daniel H. Pink explains:

> Too many people hold a very narrow view of what motivates us. They believe that the only way to get us moving is with the jab of a stick or the promise of a carrot. But if you look at over 50 years of research on motivation, or simply scrutinise your own behaviour, it's pretty clear human beings are more complicated than that […] we do things because they're interesting, because they're engaging (Pink, 2011).

While this article has compared the current legal structure relating to the authorship and ownership of patent and industrial design rights in the work place, and assessed the various criticisms against it, the question introduced at the beginning still begs to be answered: how might we justify the patent and industrial design rights that accrue to the employer? By exploring a range of alternative options, this article will attempt to demonstrate that a full corporate ownership of patent and design right is certainly more practical to business operation.

Full Employee Ownership

On one end of the allocation spectrum, the IP right could be awarded to the employee with no limitations attached so that the employee might be able to use it for whatever he wishes, including transferring it to a third party or even to the employer.

To begin with, it is important to recognise the valuable resources the employers invest in the employee's creative talent. Not only do they pay the salaries, they also provide a working environment and the materials and other resources needed in the creative process. In the words of Hershovitz (1995), "the modern industrial research laboratory is not a honeycomb of office cubicles where inventive employees toil independently, instead, the employees mostly work on individual projects, which frequently are a collaborative effort resulting from both formal and informal brainstorming sessions. While the resulting product might owe its origin to the brilliance of the employee, it should also be understood that, but for the employment relationship provided by the employer, the employee might have been unable to create the product.

Likewise, there ought to be a correlation between the party who bears the cost and risks of production, and the tool that enables the party to limit potential infringers (Bar-Gill, 2004). If the law were to allocate the design right to the party who did not bear the financial costs and risks associated with creating and commercialising the design, it will not only be unsuccessful in its desire to create incentive for creating the work, but it might actually be providing a disincentive (Birnhack, 2009).

It is instantly obvious that the typical risk bearer in the workplace is the employer; it would be essential to highlight the advantages of having the employer as the risk bearer rather than the employee. Compared to the employee, most employers have better experience, understanding and awareness of the market behaviour, and even greater resources. A typical employee does not like risk and tends to appreciate the financial security provided by his or her salary (Towse, 2003). Most employees, especially those whose source of revenue depends upon creating creative works, are less familiar with the market sector as they spend most of their time occupied in the creative department rather than in the marketing unit. The employer commercialises the design and takes on the responsibility and cost of marketing the creative work. Furthermore, in most situations, the employer may manufacture and market various products. He will have the ability to cross subsidise the products and combine the individual risk together, and in so doing, he dilutes the separate risk (Birnhack, 2009). It might be that four out of five products will hopelessly fail in the market, but the fifth product might be a hot item in the market. A company which owns all five products can dilute the risk in each product, meanwhile the employee that owns a single patent may be unable to do same.

Additionally, the employer also has a significant interest in the design right to the extent that trade secrets are typically encompassed in the product development. An employer's interest in a design rises in direct proportion with the amount of exclusive information used in developing the product (Hershovitz, 1995). A trade secret is extremely valuable because it gives the possessor an advantage over the competitors who are unaware of the trade secret (Hershovitz, 1995). If the employee has the full rights to the patent that

incorporates the employer's trade secret, he or she might, by just distributing the patent, divulge the employer's trade secret, and in so doing he might potentially cause the employer's business incalculable damages.

Joint Ownership

A second possibility will be to award the initial ownership of the patent and design right to both parties, that is, there will be joint ownership between the employer and the employee. The consequence of this is that; Firstly, each co-owner may utilise the right without the consent of the other right owners. If there is a disagreement between the employer and employee, either party will still be able to use the right without requiring an agreement. Secondly, a co-owner will need the consent of the other co-owner to grant a licence, assign or mortgage their share of rights. And in the event a co-owner dies, the deceased share in the intellectual property right may devolve to his representative.

A serious weakness with this is the possibility of 'holdup' costs (Meyer, Milgrom and Roberts, 1992). The employee might refuse to provide his consent for the employer to, for example, license the right, and frustrate the operations of the employer. If an employee were capable of holding up an employer's operations, a major effect might be an underinvestment in research and development (Merges, 1999). Like Merges observed, "common ownership of complementary assets solves the holdup problem and promotes socially beneficial activities".

Furthermore, joint ownership of right might weaken the effectiveness of the employer. There is more efficiency if the intellectual property rights are collectively owned; it gives the firm freedom of action. Giving the employer absolute control of the intellectual property rights is likely to "improve efficiency through aggregation" (Merges, 1999). However, in a joint ownership scenario, exploitation rights might need to be handled contractually and with written consents come complications on limitations, obligations, and so forth.

If individual employees partly owned intellectual property rights in the products they develop, the process of dealing with the product will be extremely complicated and financially lucrative deals might hardly ever be struck. Jointly owned intellectual property rights will face challenges at every exploitation stage and the end result is likely not to be optimal for all the parties involved. For instance, if involved in litigation, most countries will require both owners to be represented and if there is no common interest to sue, there is bound to be great amount of frustration. By not exclusively owning the right, the employer might be unable to develop favourable partnership and licensing relationships, and collaboration and cross licensing will be challenging (Andersen, 2003).

Award Ownership to Employee, Acknowledge Employer's Right

In this allocation possibility, the ownership right will be awarded to the employee but the employer will have a non-exclusive and non-transferable right to use the work for free. This possibility is identical to the American Patent law "shop right" (Neumeyer, 1971). This structure finds its origin in principles of equity and fairness and although quite limited in scope, it enables the employer to utilise the invention without transferring it to third parties.

One of the potentially devastating effects of this option is the limited transferability of the employer's right. A prospective investor or purchaser might have to acquire the whole business for those rights to be transferable. The sale of all the assets and stock of the company, or a merger, might preserve the transferability of the right, however anything less might make the transferability less definite. The uncertainty of intellectual property ownership in a target company will undeniably make any investor or purchaser concerned about potential exposure to litigation (Zimmerman, N.D). Furthermore, since the employee has an independent right to exploit the invention, he could sell, license or assign his design rights to a competitor. This would definitely result in serious consequence in the marketplace and for the employer's business.

Conclusion

In conclusion, jurisdictional approach of Nigeria and Kenya to the ownership of design and patent right may be appreciated as an attempt to find a balance between efficacy and fairness. It is quite obvious that both the employer and the employee are somewhat entitled to the patent and design rights that accrues because in the context of Locke's philosophy, they both added some sort of labour to the resources. However, the current laws are certainly the more practical structure. Full ownership, joint ownership, and the "shop right" structures have been considered and it is apparent that these options will definitely disrupt and possibly discourage the commercial efforts of honest businessmen. Thus corporate ownership of patent and design right at the expense of the individual author seems to be the more practicable solution. Nevertheless, this legal environment is definitely not so unfair as to stop designers from seeking jobs in research and development firms. The employees may make significant efforts to protect their interest by creating inventions at home, during nonworking hours and without the employer's resources.

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THE SUITABILITY OF INTERNATIONAL INTELLECTUAL PROPERTY LAWS FOR PROTECTING TRADITIONAL KNOWLEDGE AND INDIGENOUS INNOVATIONS IN AFRICA

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Abstract

This article analyses how international intellectual property (IP) laws of African countries can be utilised as a tool for advancing indigenous innovation and protecting traditional knowledge (TK) in the following steps: Section I examines the relationship between innovation and IP, with special focus on the contradictions between the definition of innovation in TK and formal IP law, by reviewing previous literature on the topic. Section II identifies the legal principles that are best able to reconcile IP regulation with public interests like TK and indigenous invention, through philosophical examination of relevant theories and doctrinal review of the provisions of relevant multilateral treaties. Section III evaluates the extent to which multilateral IP laws accommodate TK and innovation, by doctrinal analysis of relevant patent and copyright laws. Section IV draws conclusions and recommendations on how IP law can be made a more effective tool for advancing indigenous inventions and TK in African countries.

Introduction

In examining the relationship between intellectual property rights (IPRs) and development, the important role that traditional knowledge [TK] plays in sustainable development is often overlooked. For developing countries in Africa that are yet to develop much modern intellectual property [IP] protected technology, but have acquired a lot of indigenous knowledge, enhancing the capability of people to innovate and gain from TK plays an important role in advancing national development.

The main question this brings up in IP regulation is whether indigenous knowledge and innovation can be defined as 'inventions' that can be protected under IP regulations? Analysis of this question has varied between those who adopt a narrow definition of inventions as the products of research in a laboratory and consider IP law as being an inappropriate forum for protecting TK; to those who view modern IP systems as being capable of sustaining the development of TK (Mgbeoji, 2001, p.169-170). This article adopts the latter approach

whereby TK, indigenous innovation, and IP are not seen as irreconcilable, but rather as concepts that can be integrated, through the redefinition of IP norms and the adoption of alternative legal instruments, to accommodate TK and indigenous innovation. The focus is on the relevant multilateral IP agreements involving Africa, which affect TK, specifically provisions relating to patents and copyrights.

Definition of IP

IP can generally be described as that which results from the mental labour of the human mind. IP law has been defined as that which "regulates the creation, use and exploitation of mental or creative labour" (Bently and Sherman, 2004, p.1). IP encompasses the idea that a person may have ownership not just of physical property, like a house, but of the results of his or her intellectual endeavour. For such creations of the mind "the state confers a statutory monopoly for a prescribed term to prevent their unauthorised exploitation" (Blakeney, 2009, p.22) described as intellectual property rights [IPRs]. Articles 1-5 of the World Trade Organisation's [WTO] International Agreement on Trade Related Aspects of Intellectual Property Rights *[TRIPS]* (1994), protects IPRs under five main categories: copyrights, trademarks, geographical indications, industrial designs and patents. This examination focuses principally on patent and copyright law, as forms of IPRs that affect TK.

Some have defined IPRs in terms of the formal characteristics of the right granted as a right: "(i) that can be treated as property; (ii) to control particular uses; (iii) of a specified type of intangible asset" (Spence, 2007, p.12-13). Different justifications have been put forth for IPRs, such as Hegel's theory of IPRs as an inherent human right, and Locke's theory of IPRs as property, and a necessary incentive to advance innovation (Drahos, 1996, p.13-90). This article defines IPRs as *'a social product . . . [with] a social function'*. Based on the theory of Instrumentalism, which views IPRs as tools meant to advance certain public objectives and functions, there is greater scope for moulding IP protection to maintain and advance public interests including TK.

Definition of Traditional Knowledge

Traditional knowledge shouldn't be seen as knowledge that is static or antiquated, but rather as a process that refines knowledge every day in our daily lives. Nor should indigenous knowledge be considered as natural phenomena that are in the commons available for all to use. The fact is that considerable intellectual activity has been put in by the custodians of TK, thus TK is the product of purposeful investigation (Mgbeoji, 2010, p.135). This is reflected in the contributions of TK to subsistence farming and in the development of traditional medicines.

Definition of Indigenous Innovation

This article defines indigenous innovation as developments and understandings that results from the practical application of indigenous knowledge, applying local methods such as adaptation, replication and incremental improvements, by indigenous peoples.

Table 1: Conflicting Nature of IP and TK

Intellectual Property	Traditional Knowledge
Privately Owned	Owned collectively by a community, or other group of persons
Private Knowledge: Use and Access to Knowledge limited by holder of IPRs	Public Knowledge: Use and Access to Knowledge Open within Community
Protection based on novelty, inventive step and utility, scientific proof and written records	Protection based on custodial action of a community over time; May lack scientific proof; Often transmitted orally
Adopts particular western interpretations of knowledge, ownership, authorship and property	Adopts unorthodox interpretations of knowledge, innovation, ownership, authorship and property
Protected via all inclusive standards and norms (one size fits all) mainly through multilateral treaties	Standards and norms for protection differ based on context (differentiation), usually through national or regional laws and policies
Promoted by national treatment (NT), most favoured nation (MFN) and reciprocity principles (See Articles3&4 TRIPS Agreement)	Promoted by access and benefit sharing, prior informed consent principles (See Articles 15 & 8j CBD; Nagoya Protocol)

The above analysis indicates that though challenges exist in the current IP framework for accommodating TK and indigenous innovation, such challenges can be surmounted by: defining new to include TK passed on orally or publicly held; redefining inventions to include knowledge derived from informal processes, and broadening the right to hold IPRs to include collective entities such as communities.

Importance of TK and Inventions for Development

For many centuries, human beings have been producing knowledge and strategies enabling them to survive in a balanced relationship with their natural and social environment. Consequently, for any IP law to sustain development in indigenous settings, it must recognise, protect and advance indigenous knowledge and inventions. Indigenous innovation and TK are important for capacity development in such settings because they are based on a bottom-

up approach that encourages "development from within, based mainly, though not exclusively, on locally available resources, values, institutions and knowledge" (Kendie and Guri, 2010, p.55). The failure of IP laws, based on western definitions of innovation, to generate development and indigenous innovation in Africa's developing countries emphasises the need to rethink the norms and designs of these IP regulations.

Principles for Reconciling IP, TK and Indigenous Innovation Legal Principles

IPRs are tools for advancing public interest

This has been affirmed by legislation, jurisprudence, and literature at the international and national levels. In the case of *Teva Canada Ltd. v. Pfizer Canada Inc.*, (2012) the Supreme court of Canada affirmed that the patent system is based on a bargain, or quid pro quo: by which the inventor is granted exclusive rights in a new and useful invention for a limited period in exchange for disclosure of the invention so that society can benefit from this knowledge.

IPRs are not static, but continuously evolving

"[IP] is hardly a static conception, but is in a state of constant evolution and reconsideration. The first English and Venetian laws were public in nature, a means of harnessing foreign technologies, or of regulating and censoring domestic printing. But by the nineteenth century, [IP] had become classified as a type of private law, conferring private property rights on the few." (Dutfield and Suthersanen, 2008, p. 14). The 21st century has witnessed greater emphasis on the impact that IP protection has on non-economic and social aspects, including education, health, environmental protection and culture. The evolution of new forms of IPRs such as PBRs, and rights over digital technology are examples of new forms of IP protection designed to meet the needs of new technologies.

Considering that public interest (including the right to protect and develop culture through TK and indigenous inventions) is one of the objectives that IPRs should advance, and that IPRs are not static in nature but rather evolve to meet the needs of society at specific times, current forms of IP protection can be modified so as to include traditional and indigenous knowledge.

One size does not fit all in IP regulation

Several economic studies have been conducted on the impact of IP protection on development (Ahn, Hall, and Lee (Eds.), 2014; Milchior, 2015, p. 717). These studies do not provide reliable evidence that increasing IPRs definitely lead to greater socio-economic progress. Rather, they indicate that the impact of IP protection greatly differs between various countries and contexts (Wong and Dufield, (Eds.), 2011, p.3). The provisions of contemporary IP laws indicate

that though they agree that IPRs should lead to development, a large degree of variance exists on what is the best framework by which to harness IP law to achieve developmental objectives. For just like people have to wear clothing of different sizes depending of their sizes, 'one size does not fit all in IP regulation'. This makes it important for individual countries to assess the implications of current and proposed IP regulation in the context of their national development goals. African countries should identify what will advance their public interests in TK, local innovation, national capacity building and development; evaluate the potential impacts of current and future IP systems on such interests based on impact assessment; then tailor their IP laws to accommodate such public interests.

Development advances social, not just economic interests

What is defined as development may vary greatly between countries. An overview of the provisions of contemporary IP regulation indicates that while agreeing that IPR should lead to development, a large degree of variance exists on what is the best framework by which to harness IP law to enhance development. For the sectors that are considered necessary for development will vary, depending on the context of analysis. The interests to be included will differ depending on the overlying geography, state of economy, culture and social interests of the country, or region seeking progress (ILC Report, 2006, p.23, par.34). Because development is not a fixed formula, every country requires some flexibility to contextualise their application of IP laws. A historical overview of national IP laws and policies confirms this need for contextualisation, for countries have changed their IP laws and policies at different stages of economic development (CIPR, 2002, p.18-19). Based on this principle, IP regulation can only aid development in African countries, where it grants those countries: 'maximum freedom to protect and maintain TK, indigenous innovation and cultural heritage; while advancing their national capacity to improve all these areas.' (Sen, 1999; Nussbaum, 2011).

Provisions for Protecting TK and Indigenous Knowledge in International Law

Space within multilateral IP regulations-TRIPS and UPOV

Though essentially favoring the further expansion of current IPR regimes, there are some provisions in TRIPs that can be exploited by communities and countries interested in protecting their interests against those of dominant industrial-commercial forces:

Article 8 allows for legal measures to protect public health/nutrition, and public interest; though cultural protection is not explicitly built into this, it could be justified as being in "public interest".

Article 27(2) allows for exclusion, from patentability, inventions whose commercial use needs to be prevented to safeguard against "serious prejudice" to the environment. This is somewhat convoluted, because a country will first need to determine such serious prejudice, justify the prevention of commercial use, and then only be able to justify non-granting of patents;

Article 27(3) allows countries to exclude plants and animals from patentability, and also plant varieties, so long as there is some other "effective" form of IPR to such varieties. As mentioned above, what is "effective" is likely to be determined by powerful countries, in which case the almost patent-like regime being advocated by UPOV could well be pushed. However, an exceptionally bold country could well experiment with completely different *sui generis* systems, and face up to any charges that are brought against it at WTO.

Article 15.1 of the International Convention for the Protection of New Varieties of Plants of the Union for the Protection of New Varieties of Plants [UPOV] (1991) states that PBRs shall not extend to acts done privately and for non-commercial purposes; acts done for experimental purposes and; acts done for the purpose of breeding other varieties. Such exceptions may give countries leeway to domestically research and breed plant varieties to meet national food security needs, even without the permission of the breeder.

Space within non-IP regulations

Article 8j of the Convention on Biological Diversity [CBD] (2000) requires countries to respect and protect indigenous and local community knowledge, ensure that such communities are asked before using their knowledge for wider society, and further ensure the equitable sharing of benefits arising from such use. Built into this provision are the seeds of a radically different vision of protecting knowledge and generating and sharing benefits from it. Follow up agreements to the CBD such as the Nagoya Protocol (1993), and the ITPGRFA confirm this multi-faceted view of development.

The importance of benefit sharing in an African setting is illustrated by the San Hoodia case concerning the San peoples, also known as Bushmen of the Kalahari, of South Africa, and their TK of the appetite-suppressant properties of the Hoodia succulent plant, used as a substitute for food and water when hunting. In 1995, a South African research institute, the Council for Industrial and Scientific Research [CSIR], successfully isolated the appetite suppressant properties of the plant, and filed for a patent. Though South Africa was a party to the CBD, the CSIR never made contact with the San. Instead, they sub-licensed their discovery to firms in Europe and the United States for significant fees. A vigilant local NGO eventually informed San leaders that their TK had been used in a patent application and that they could either challenge the patent or demand a benefit sharing agreement. They chose the latter option. In March 2003, the San and the CSIR signed a historic agreement which will give the San

6 per cent of all CSIR royalties received from licence-holders and 8 per cent of all milestone payments. (Schroeder, 2010, p.107)

Based on Article 8j CBD, it is proposed that in addition to conventional criteria for IPRs such as novelty, etc, the following conditions should be required for IP applications relating to TK: source (country/community/person) of the material or information that has gone into the produce/process for which an IPR is claimed; proof of prior informed consent from the country and community of origin (as per Articles 15(5) and 8j of the CBD); and details of the benefit-sharing arrangements entered into with the community of origin, wherever applicable (as per Article 8j of the CBD).

Article 15(1) ICESCR recognises the right of everyone to: take part in cultural life; and benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author. In Article 15(2) State Parties commit to take actions necessary for the conservation, the development and the diffusion of science and culture.

Space within human rights law

Article 27 (1) of the Universal Declaration of Human Rights [UDHR], Right to Participate in Cultural Life, which states that: "Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits". While Article 27(2) establishes that "Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author".

The right to culture is based on the theory that all human beings have the right to express themselves through traditional knowledge and cultural creativity. Such knowledge is an extension of the human personality that deserves to be recognised, preserved and rewarded in a dignified manner. TK such as folklore and stories can be considered as artistic productions of indigenous people, which must be protected. Consequently, IPRs cannot be protected in an isolated manner, as if they do not affect, nor are affected by, the provision of other laws or human rights [HRs]. Rather, IP regulations must fully consider the implications of protection for cultural HRs, including TK and indigenous innovation (Chon, 2006, p. 2821).

Even where IPRs are justified as a form of property, under Locke's theory, it must be remembered that the intellectual property protected by IP is not meant only to reward the labourer or creator of knowledge, but must also maintain the commons of which TK forms a part. In the words of Andrei Marmor (2007): "There are common goods which, once they exist, give rise to distributional rights. Consider the example of culture. Once a given culture exists, it may well be the case that the cultural resources of the community ought to be distributed according to a just and fair scheme. People may have a right to a fair share of

the cultural assets of their community, that is, even if they do not have a right to culture." (p.243)

A more prescriptive recognition of culture and indigenous knowledge as HRs is contained in the UN Declaration of the Rights of Indigenous Peoples [UDRIP] (2007). The Declaration affirms the right of indigenous peoples, as a collective or as individuals, to the full enjoyment of all HRs and fundamental freedoms as recognised in the Charter of the UN, UDHR and international human rights law (ibid.: art. 1); the equality of all peoples and individuals, and their right to be free from any kind of discrimination, in the exercise of rights based on indigenous origin or identity (ibid.: art. 2). UDRIP asserts peoples' right to freely pursue social and cultural development (ibid.: art. 3); along with the right of people to maintain and strengthen their distinct social and cultural institutions, while retaining their right to participate fully, if they choose, in the social and cultural life of the state (ibid.: art. 5). Also people have the right not to be subjected to forced assimilation or destruction of their culture (Ibid, art. 8).

Based on the above provisions, where innovation is defined under IP regulations so as to exclude TK and indigenous inventions, in a way that limits the development of indigenous innovations, such IP laws will be considered as discriminatory and against human rights. Article 31 of the UDRIP confirms that indigenous knowledge is not something static, or ancient having no relevance for the contemporary technological development for people have "the right to maintain, control, protect, and develop cultural heritage, traditional knowledge, and traditional cultural expressions, as well as the manifestation of science, technologies and cultures"

Implications for Advancing TK and Innovation in Africa

- The preconditions for patenting do not rule out TK from IP protection.
- Theories and regulations on interpreting international treaties, suggest the norms contained in the EPA may affect the interpretation of IP norms regionally between West African countries (See Article 41 VCLT).
- For "as long as an invention can be shown to be differing from the actual method used in a TK and involves an inventive step it can be patented." This perspective has been confirmed by the decision of the Indian Supreme Court in the case of (Bishwanath Prasad Radhey Shyam vs. Hindustan Metal Industries, 1992). Thus where TK isn't classified as prior art, it can still be qualify for protection under modern IP systems.
- Moreover, the purpose and objectives of IPRs, as stated in Article 7 TRIPS and Article 8j of the CBD confirm that the overriding purpose when applying the patent system to bio culture should be the re-interpretation

of IP provisions so as to respect, preserve and maintain the knowledge of indigenous and local communities.

- Sui generis systems may be designed under Article 27.3(b) TRIPS
- Prior Informed Consent, Access and Benefit Sharing, Disclosure of Origin Requirements, may be applied to TK and indigenous innovation.

Conclusions and Recommendations

Holistic Definition and Implementation of IPRs Development Objective: Modern definitions of development and innovation, as stated in soft law/non IP agreements such as the Declaration on the Right to Development, (1987, Articles 1.1, 2.2, 3.1, 6.3, 8.1, & 8.2), the SDGs (2015), and the ICESCR should be taken into consideration in defining rights and responsibilities under IP and trade laws. These agreements acknowledge that development is not just about economic growth, but includes advancing the social, cultural and political well-being of people. Under this approach analysis of IPRs will not just focus on the way states treat foreign investors, but will also include examining the investor's responsibility to indigenous communities in the host state, as legal stakeholders in IPRs. This could be done by adopting performance indicators for prerequisite testing to measure the potential impact of regional and multilateral agreements on TK and innovation in the continent (WWF and CIEL, 2001, p. 23-24)

Compulsory Legislation and Implementation of Prior Informed Consent, Fair Access and Benefit Sharing Schemes: Contemporary IP agreements treat environmental, social, political and cultural advancement as discreet areas of activity. They do not seek to integrate them into one holistic vision of development. The result, as can be seen in some of the contentious projects funded by the World Bank and in some attempts at expanding corporate social responsibility practices, is that environmental and social, including human rights issues, are often seen as 'costs' of doing business rather than as an integral part of the development process.

Ensuring socio-economic advancement for indigenous people will be enhanced by including binding provisions for access and benefit sharing in national IP legislation. Procedures for prior informed consent should also be developed in cooperation with all the stakeholders, including farmers and local and indigenous communities.

Re-defining the core concepts of relevant IP regulation to support development: For example, concepts like "novel" and "invention" must be carefully defined, to ensure that genetic resources are not removed from the public domain. To protect traditional knowledge from misappropriation, patent offices should examine sources such as oral testimony, visual evidence, and material held in gene bank deposits when applying the "novelty" requirement. Careful definition of core concepts will avoid strengthening IPRs further than required

by the TRIPS Agreement, and reduce its potential to undermine development objectives.

Promotion and Protection of Traditional Knowledge and Innovations: Domestic research and innovation will have greater impact on advancing sustainable development in Africa, than technology transfer. For "technology adoption alone is no longer sufficient to maintain a high growth scenario, rather innovation is now crucial for catching up to high income countries." (GII, 2015, p.4) Consequently, African countries should adopt policies aimed at developing TK and indigenous innovation. A useful instrument in protecting TK is the provision of databases to record TK and informal inventions. African states should enact regulation legally protecting traditional knowledge inventions and adopt policy measures to encourage research, development and innovation in this area (UN Post, 2015).

Development of sui generis systems to support development: Flexibilities inherent in the TRIPS Agreement's, allowing countries to adopt "effective" sui generis protection of plant varieties, should be fully utilised by ECOWAS countries. Examples of such unique rights could be allowing for Farmers' Rights to be compulsorily protected at all levels, especially their right to save and share seeds. India presents an example of an emerging economy that has adopted a sui generis system, helpful for advancing the interests of both indigenous stakeholders and investors.

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BALANCING ACCESS AND INNOVATION IN PATENT ENFORCEMENT: A COMPARATIVE ANALYSIS OF THE ROLE OF THE JUDICIARY IN KENYA AND INDIA

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Abstract

Courts play a critical role in enforcing patent rights. Often this role requires balancing of the rights of the patent owner and that of the public generally to access the invention. For pharmaceutical and medical related patents in particular, exercise of judicial authority frequently requires the balancing of two conflicting rights, that is, property rights versus human right to health. This article seeks to provide a multi-dimensional approach on the latitude courts in Kenya and India have resorted to in resolving and balancing the conflicting interests of pharmaceutical patent owners versus the right of the public to access medicine at affordable prices.

Introduction

This article seeks to explore and address how much latitude courts in developing countries have in balancing incentives and access to medicines in patent enforcement cases. India and Kenya will form the focal point of the article.

On one hand, the importance of patents cannot be underscored enough. Patent provides critical economic incentives in the pharmaceutical and other technological industries. The cost of research and development (R&D) required to bring a new drug to the market is high, currently estimated at over $1 billion. According to a survey conducted by Forbes in 2013, most big pharmaceutical companies are developing more than one drug at a time which often drives up the cost to about $5 billion.[1]

Given the high nature of investment involved, players in the pharmaceutical industry justifiably demand the highest and longest form of protection available through IP regimes particularly patent protection. Without adequate economic incentive, limited investment may arguably be channelled into this critical sector which would adversely affect healthcare standards and technologies. Therefore upholding the economic incentives for patent owners is a legitimate concern.

On the other hand, patents grant to the patentee monopoly like rights for a limited period to make, use, sell, and offer to sell or import the patented

pharmaceutical product or process. With these rights, the patentee controls distribution and drug pricing, which can both have a significant impact on access. Access to essential medicines has been recognised by the World Health Organisation (WHO), various international legal instruments and several Constitutions around the world, as a necessary component to the right to health.

For most developing and least developed countries, healthcare needs continue to be a current problem. African countries have a high disease burden for HIV/AIDS, malaria, neglected tropical and other diseases. As a result, achieving the highest attainable standards of healthcare is a key national concern for most African countries. This goal, out of necessity, requires access to affordable medicine which may arguably be hampered by the monopoly-like rights owned by patent owners, therefore when determining patent infringement cases involving pharmaceuticals, balancing innovation with access is critical.

In addition, often, courts in developing countries are called upon to enforce patents belonging to foreign nationals, since the inequality in the distribution of pharmaceutical patents is quite significant with developed countries owning the lion's share of patents through large multinational pharmaceutical companies.[2] Nonetheless due to international obligations, courts must give equal treatment under the law to foreign patent owners, which may conflict with national interests of that particular developing country.

Finally, while intellectual property (IP) enforcement cases are determined by courts at national level, there is a lot of influence from international treaties and community. In particular, IP treaties from World Intellectual Property Organisation (WIPO) (Paris Agreement) and the World Trade Organisation (WTO) (TRIPs Agreement) have had the most impact. TRIPS has set minimum standards which all contracting states have complied with, and incorporated in domestic IP legislation. Accordingly, courts must comply with these minimum standards; and any existing latitude and flexibilities for improving access to medicines can only be applied to the extent allowed by law.

It is for these reasons that courts in developing countries like Kenya and India face many daunting challenges in balancing incentives and access in patent cases involving pharmaceuticals. While it is not a direct role of any court system to address healthcare standards in a country, judgments and other judicial decisions in any country are not made in a vacuum. Judgments have socio-economic effects on citizens and patent owners who are quite often foreign. Therefore blindly enforcing all pharmaceutical patents may negatively affect development especially a country's health sector and judges ought to balance between the need for incentives and access.

This article seeks to provide a multi-dimensional approach on the latitude courts in Kenya and India have resorted to in resolving and balancing the conflicting interests of pharmaceutical patent owners versus the right of the public in general to access medicine at affordable prices. From the perspective

of these two countries, this article analyses how this role has played out in courts in selected cases.

Part I briefly discusses international patent regime and the attendant obligations and influences that come from the key international patent treaties. Part II explores innovation versus access questions, theories and justifications. It then delves into the flexibilities available under the (TRIPs) to improve access to medicines. Part III examines national responses and approaches in Kenya and India in dealing with pharmaceutical patents versus the right to health of its people. Selected case law from these two jurisdictions are examined. In the final part, the article makes conclusions and recommendations.

A Brief Overview of International Patent Law

Generally, inventions are patentable if they meet minimum threshold requirements of novelty, inventive step and usefulness. A patent is granted pursuant to national patent laws.[3] Under the territoriality principle, the scope of patent protection is limited to the territory of the country in which a particular patent is granted.[4] Accordingly, most national governments around the world including Kenya and India have patent laws and regulations to govern patent registration, protection and enforcement. A patent grants to the patentee rights to exclude others from making, using, selling, offering for sale or importing the patented product or process without the patentee's authorisation. These exclusive rights are enforceable within the national jurisdiction of the country in which that patent was granted, through local national court processes and other dispute resolution mechanisms. Thus, for instance, patent infringement of a Kenyan patent is determined through Kenya's court system and laws.

However, most national patent laws are not autonomous in that they are influenced and often determined by minimum standards set by international treaties. There are several international treaties dealing with IP under the auspices of the WIPO and later by the WTO. These international treaties are important internationally and also at national levels because they have set minimum standards which significantly shaped and created uniformity of patent laws in most countries around the world including India and Kenya.

Paris Convention

WIPO's Paris Convention for the protection of Industrial Property (Paris Agreement") was first signed in 1883. It has been revised severally and currently has 175 signatories. It provides for the protection of industrial property which includes patents, trademarks, industrial designs, utility models, appellations of origin and protection against unfair competition. The Paris Convention established minimum principles and standards of IP protection without interfering with the territoriality nature of IP. Under its national treatment principle which sought to eliminate discrimination against foreign owned IP,

contracting countries are required to offer foreign nationals equal treatment as its own nationals. In addition to creating industrial property protection, the Paris Convention establishes certain limitations to IP protection such as compulsory licensing and other exceptions.[5]

The Paris Convention has been criticised for lacking adequate enforcement mechanisms. Further, that by allowing national treatment, contracting countries could elect whether to offer IP protection or not for a particular product or process provided such a law was enforced uniformly as against national and foreign innovators. It is this principle that India adopted for over 30 years up to 2005, to deny patent protection to all pharmaceutical products.

TRIPS Agreement

It is partly because of these criticisms that IP protection was deliberated as a trade issue under the WTO and subsequently, the TRIPs Agreement was signed isn 1994 to provide more uniform and effective international IP standards. Articles 27 – 38 of TRIPs Agreement sets out the minimum patent standards.[6] TRIPs establishes minimum patent rights that member states must grant patentees which are:

> a) where the subject matter of a patent is a product, the right to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
>
> b) where the subject matter of a patent is a process, the right to prevent third parties not having the owner's consent 'from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process."[7]

WIPO versus WTO

Arising from the differences in the powers granted to each organisation, their respective treaty provisions and institutions governing each, there are significant implications arising from the move and current sharing of multilateral IP protection and governance from the purview of WIPO only to WTO also. First, national treatment principle differs from the TRIPS Agreement to the Paris Convention. Unlike the flexibilities under Paris, the set minimum standards under TRIPS are applicable to all member states without exception. Under WIPO regulation, a country was allowed to set certain IP standards like India's exclusion of pharmaceutical products from patentability provided such standards were enforced uniformly as against nationals and foreigners. TRIPs removes this flexibility and requires all member states to apply uniform minimum IP standards.[8] Second, the move from WIPO to WTO is significant because of the effective dispute resolution mechanisms by WTO. WTO IP trade disputes can be resolved under WTO's Agreement on Dispute Settlement

Understanding (DSU) which established the Dispute Settlement Body. It also has an established seven member Appellate Body to handle appeals.[9]

WIPO on the other hand lacks a similar rules based dispute settlement mechanism. Its Arbitration and Mediation Centre offers alternative dispute resolution (ADR) options including mediation, arbitration, expedited arbitration and expert determination.[10] Critics of these ADR processes argue that they are inadequate and the IP rights granted in the various WIPO Agreements could not be effectively enforced. Without a multilateral dispute mechanism process, countries often had to take individual unilateral action in reaction to IP infringement or for failure/refusal to protect their national's IP by foreign governments. For instance, the US under section 301 of the Trade Act of 1974 (popularly known as "super 301") frequently took appropriate trade and related action including retaliation against foreign governments which violated international trade agreements including under WIPO Agreements.[11] This made enforcement cumbersome and dependent on the relative power a country yielded internationally. WTO resolved this challenge by setting up a proper multilateral dispute resolution mechanism available to all member countries.

However, by requiring all countries to uniformly apply minimum IP standards, TRIPS constricted the space available for developing countries to take steps necessary to address development challenges. Its reduced flexibilities discussed below are available in limited conditions only.

Patents: Innovation versus Access

One of the key justification for IP protection generally is the need to promote innovation by providing economic incentives and granting to inventors the right to control exploitation of their invention. But an equally important ideal is the need to provide access to the invention to consumers and the public. For pharmaceutical patents access is a critical issue in healthcare because access to essential medicines and procedures often means life or death. But without adequate IP protection companies may be less willing to invest in R&D required in the pharmaceutical sector. Therefore from the perspective of innovation and access, patents can have both a positive and negative impact on development as discussed below.

The theories, justifications and implications of patent protection in closed versus open economies differ. An open economy[12] refers to a country that engages in international exchange of goods and services while a closed economy is a more self-contained economy with limited contribution to international trade.[13] Access and innovation issues differ in closed versus open economies. In an open economy, stronger IP protection arguably stands to benefit the IP rich countries[14] who export the technologies. The inequality in patent distribution has impacts on the development and access to essential patented products and processes for less developed economies. Due to international obligations

to recognise set minimum IP standards during the term of the patent, less developed countries cannot apply available technologies to develop their local industries without first obtaining a licence.

In a closed economy, proponents emphasise the innovation element provided by strong patent protection. A patent is considered a social contract.[15] Therefore in return for disclosing an invention, the patentee gets exclusive rights for a limited period of time. In this way, advancements in pharmaceutical and medical sciences are facilitated and promoted since the patentee must fully disclose the components of the invention and best mode of practising the invention. Other innovators in the industry can use the disclosed invention in their research to create other drugs and treatments.[16] In this way duplication of research, is avoided as the details of the invention are available through a patent office.

In addition, patent plays a crucial role of providing economic incentives in the form of exclusive rights to innovators. As stated above, R&D for a new drug is estimated to be as high as 1 to 5 billion dollars. The high cost of R&D is attributed to the time and risk associated with developing a new drug. Even after successful innovation, pharmaceutical products and processes must be subjected to regulatory approval. As a result, only a small fraction of products and processes make it to the market due to failure at clinical trial stage and rejection by regulatory authorities.[17] The success rate differs depending on the therapeutic class with success varying from 8 to 24 percent.[18] Such a low success rate further escalates the cost of new drugs, as consumers are forced to pay higher prices to compensate for the failures and R&D costs of the drugs that did not make it to market.

With patent protection, the patentee has 20 years or more of exclusivity to make, sell and authorise use the invention. During this period of protection, the patentee can recover the cost of R&D and turn a profit. This includes compensating financially for the R&D cost of the other drugs that did not make it to market. There are arguments that without an effective patent system, free riding would increase and this would hinder progress and innovation as fewer companies would have incentive to invest in costly R&D required for developing new drugs, vaccines and treatment methods. Under the patent system a patentee has competitive advantage and is able to commercialise the invention at the exclusion of all others for a limited period.

Access to Medicines

On the other hand of the debate is the access counter argument. There is evidence that pharmaceutical patents can have negative impact on access and availability of medicines.[19] A patent grants monopoly like rights to the holder who can determine drug pricing and availability.

First, challenges to access for medicines for developing countries including Kenya and India can be viewed from three main areas. Perhaps the most

significant obstacle to accessing treatment is cost.[20] For instance, treatment for HIV/AIDS gained global attention largely because of the fatal nature of the disease and the massive numbers of HIV infections and therefore numbers of people in need of treatment. At the beginning of the AIDs crisis in the late 80s and early 90s, ARVs cost on average $ 10,000 per year, which cost was prohibitive and untenable for millions of people in developing countries who succumbed to the disease.[21] Pharmaceutical companies were accused of putting profits and patents over people; and a strong advocacy movement arose in the 90s pushing for affordable medicines for HIV treatment. The international community including international organisations, governments of several developed countries, Funds and Non-Profit Organisations responded and have significantly assisted in providing access to cheaper medicines to people living in low income countries.[22] In addition, production of generic drugs also drove prices down.[23] The cost of treatment of first line adult regimen treatment of HIV dropped to about $74 per person per year by 2008,[24] and as a result millions of people today who require treatment are receiving it.

Second, neglected tropical diseases is a significant problem without the global attention of HIV/AIDS. According to the WHO:

> Neglected tropical diseases (NTDs) blight the lives of a billion people worldwide and threaten the health of millions more. These ancient companions of poverty weaken impoverished populations, frustrate the achievement of health in the Millennium Development Goals and impede global public health outcomes. An evaluation of their significance to public health and economies has convinced governments, donors, the pharmaceutical industry and other agencies, including nongovernmental organisations, to invest in preventing and controlling this diverse group of diseases.

As stated above, there have been a lot global efforts to combat HIV/AIDS and provide access to affordable medicines. While HIV/AIDS infections and deaths have been concentrated in developing countries especially in Africa, it was still a global problem and it therefore attracted swift worldwide response from donors and also the scientific community. However, for diseases limited to poor tropical countries there is limited economic incentive to engage in R&D which has significantly limited availability of new and effective drugs and treatment.[25] There are about 14 diseases on the WHO list of neglected diseases which affect approximately one million people in poor countries.[26] Due to lack of adequate economic incentive, there is less R&D in neglected diseases leading to access problems.[27]

Third, the patent term for pharmaceutical products is a thorny issue. In theory a patent term should last for 20 years.[28] In practice, the pharmaceutical industry has adopted various strategies to extend patent terms often referred to as evergreening strategies.[29] Evergreening refers to various legal and business strategies by patentees to extend patent terms on modified forms, new delivery systems or new uses for the same drug. Strategies include protecting a single

pharmaceutical product by a string of patents or patent portfolio on the active ingredient and secondary patent on other formulations.[30] In addition superfluous modifications and improvements on the original drug are also patented further extending patent term[31] Other business related evergreening strategies include entering exclusive partnerships with generic drug producers to enhance brand value; establishment of subsidiary units as generic producers before expiry of the drug; defensive pricing strategies to stifle competition; and switching to over the counter (OTC) distribution instead of prescription for a drug whose patent is about to expire.[32] These and other strategies have significantly extended patent holders control. The table below demonstrates examples of the effectiveness of patent term extensions.

Table 1: Effectiveness of patent term extensions

Case Study	Rank	Generic Name	Proprietary Trade Mark	Maximum Period of Patent Protection
1	8	CLOPIDOGREL	PLAVIX, COPLAVIX, DUALPLAVIX, DUOCOVER	38yrs 7months 11days
2	6	VENLAFAXINE, DESVENLAFAXINE	EFEXOR, EFEXOR-XR, PRISTIQ	39yrs 8months 13days
3	13	ATORVASTATIN	LIPITOR, CADUET	33yrs 7months 1day
4	12	ALENDRONATE	FOSAMAX, FOSAMAX PLUS D-CAL	36yrs 5months 17day
5	4	CEFUROXIME	FORTUM, ZINNAT	43yrs 7months 16day
6	11	ZOLEDRONIC ACID	ZOMETA, ACLASTA	36yrs 9months 29day
7	3	CITALOPRAM, ESCITALOPRAM	CIPRAMIL, LEXAPRO	46yrs 7months 8day
8	1	OMEPRAZOLE, ESOMEPRAZOLE	LOSEC, PRILOSEC, NEXIUM	48yrs 27months
9	15	ROSUVASTATIN	CRESTOR	27yrs 10months
10	7	RISEDRONATE	ACTONEL, ACTONEL E.A.T COMBI	39yrs 3months 26day
11	9	NEVIRAPINE	VIRAMUNE, VIRAMUNE XR	37yrs 11months 8day
12	2	FEXOFENADINE	TELFAST	46yrs 8months 18day
13	5	LANSOPRAZOLE	ZOTON	40yrs 4months 14day
14	10	MELOXICAM	MOBIC	36yrs 11months 3day
15	14	OLANZAPINE	ZYPREXA	31yrs 3months 2day

Critics argue that evergreening practices are abusive as they prevent patented drugs from falling into the public domain thus delaying production of generic medicines, and acts as a barrier to access to affordable medicines. There are policy arguments that a balance between preventing legitimate incremental innovations over mere evergreening strategies will be productive. As a result of the monopoly-like exclusive rights to control the manufacture, sale and importation of patented products and processes, patentees are able to set drug prices.[33] High drug prices mean that poorer members of society cannot afford treatment thereby severely limiting access. The majority of developing and least developed countries which are net importers of drugs have been affected the

most, especially the countries without technological capacity to manufacture the drugs themselves. With longer extended patent terms, a patentee continue to control distribution of the patented drugs thereby limiting access.

Improving Access to Medicines through TRIPS Flexibilities

To address these public health challenges and disease burden, member countries of WTO can utilise the TRIPs flexibilities. As discussed above TRIPs is important because it sets minimum standards by which members like Kenya and India must operate.

TRIPs recognises under Article 7 that IPRs should be protected and enforced in a manner that promotes socio economic development. Article 8(1) further permits countries to adopt necessary measures to protect public health and nutrition. However, these measures must be consistent with the TRIPs Agreement. The limitations of compliance with the TRIPs Agreement under Article 8(1) have significantly curtailed member countries' abilities to apply TRIPS flexibilities. These flexibilities include: transition periods, compulsory licensing, public non-commercial use of patents (government use), parallel importation and exemptions from patentability.[34]

Article 27 provides for patentable subject matter and establishes exceptions for exemption of diagnostic, therapeutic and surgical methods for human and animal treatment, from patenting. For a product of process to be patentable it must be new, involve inventive step and have industrial applicability. TRIPs does not require patenting of modifications or new uses of known substances and thus patent protection can be rejected for such applications.

In addition, compulsory licensing procedures are established under Article 31 of TRIPs. A compulsory licence is one issued by a Government without authority of the patent owner to a third party to manufacture, a patented product and to use and sell it.[35] The Doha Declaration at paragraph 4 clarified that 8(1) would not prevent a country from derogating certain patent obligations under TRIPs to address public health needs. In addition in Article 31 *bis* was adopted by WTO General Council clarified compulsory licensing conditions. However, the effectiveness of Doha is limited because it is merely a Declaration and is thus not binding.

Parallel importation allows countries to import cheaper drugs from other markets. It is premised on the principle that once a patented product has been sold legitimately, the patentee's rights are exhausted and he cannot control resale of the drugs in a secondary market.

In spite of these provisions, implementation of TRIPs flexibilities to achieve access to medicines for least developed and developing countries, has been difficult and challenging. Use of compulsory licences by developing countries

is growing but still in limited numbers in spite of significant public health needs. [36] Most countries elect to proceed with caution to avoid trade sanctions and often voluntary licence agreements have subsequently been entered with the pharmaceutical company in place of the compulsory licence. At national levels, Kenya and India have both adopted these TRIPs flexibilities in different models which are discussed below.

National Responses in India and Kenya

The international IP treaties under WIPO and WTO matter at national level for developing countries like Kenya and India because they influence national IP laws. Under TRIPs, all member states including Kenya and India were required as a matter of course to adopt minimum TRIPS standards based on their membership to the WTO. Accordingly, IP laws of member states are fairly similar based on these international obligations, at least on expected minimum standards. Like other developing countries, compliance with TRIPs and other international obligations has created development challenges which include the requirement to recognise and offer protection of pharmaceutical patents even in the face of national health crises.

As IP rights are territorial in nature, in order to secure protection of a pharmaceutical product or process in different jurisdictions, for instance in Kenya and India, the patentee must file a formal patent application in each country in which patent protection is sought. The patent application must satisfy certain formal requirements and the patentee must pay patent fees. In addition to the formality requirements, the patent will be subjected to substantive examination. To be patentable, first an invention must fall under patentable subject matter. As such discoveries, laws of nature and products in their natural state cannot be patented. Second the invention must meet three basic requirements: novelty, non-obviousness and utility.[37] If the patent application is granted, the term of the patent is 20 years. However, for pharmaceutical products and processes which require regulatory approval, this term is often increased to cater for the special nature of the pharmaceutical industry since clinical trial is often required to ensure safety and efficacy of a new drug.[38] As a result, while the default patent term is only 20 years, this term has been extended by various legal mechanisms in the patent system, leading to problems in providing access to medicines. In addition the pharmaceutical industry has adopted various industry practices for extending patent term through evergreening and other strategies.

Like other IP rights, patent protection and enforcement is territorial in nature. Therefore protection only extends within boundaries of a particular country. For developing countries like Kenya and India, meeting their international obligations under WTO and WIPO to protect and enforce foreign patents while at the same time meeting their public healthcare needs has presented many challenges.

The two countries selected for case studies herein, that is India and Kenya, are both developing countries. However, it is noteworthy that they are at different stages of development. India has an advanced pharmaceutical industry and is ahead of Kenya in many ways in terms of development indicators.[39] This can be attributed in part to the strategies adopted by India that encouraged and supported the growth of its domestic pharmaceutical industry. In addition to the differences in economic and technological capacities, the legislative and judicial responses have differed. This offers a useful comparison of successful strategies adopted to balance innovation and access at domestic national levels.

National IP Frameworks in India and Kenya

India's patent legal framework

In India, patents are registered and regulated under the Patent Act which provides the requirements and procedures of obtaining a patent in India. It applies the basic tenets of patent law such as novelty, inventive step, and industrial application requirements.

The first Patent Act was passed in 1947 and it has been revised severally and replaced in 1970 and subsequently in 2005. India is a signatory to both WIPO's Paris Convention and WTO's TRIPs. Under the 1970s Patent Act, it had implemented the national treatment principle as flexibility. By exempting all pharmaceutical products from patenting, India was able to develop its own domestic pharmaceutical industry for generic drugs. This exclusion of pharmaceutical products from patenting was applied equally to inventions by nationals and foreigners thus conforming to the non-discrimination requirement by WIPO.[40]

However, when India joined WTO, it was forced to standardise patent protection in line with the rest of the WTO members. Thus at the expiry of the transition period for developing countries, India amended its patent laws in 2005 to permit patenting of pharmaceuticals and agricultural chemicals. Critics from within and other developing and least developed countries which were relying on generic drugs from India argued that TRIPs compliance would adversely affect India's pharmaceutical industry and slow down access to medicines for many developing countries. India's legislative latitude to differentiate its patent system for pharmaceuticals in favour of its own national interests is thus limited after TRIPs.[41] However, it has continued to apply the available flexibilities as discussed below.

First, India took advantage of the full 10 year transition period available for developing countries before amending its IP laws. Amendments to the Patent Act were enacted and came into force in 2005. Drugs that were already being produced in India as generics were not clawed back thus production of those drugs continued. Second, while India adopted the spirit of TRIPs provisions,

it firmly maintained in the 2005 Patent Act safeguards to promote and address public health issues such as flexible compulsory licensing requirements and ban on evergreening practices such as patenting of modifications or discovery of new form of existing known substance.[42]

In particular, section 3(d) of India's Patent Act excludes from patentability:

> the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Further section 84 provides for compulsory licences, that:

> At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:— (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India."

As a result, as will be discussed in the case studies below of the developing countries, India has retained fairly significant latitude for judges to promote access in patent enforcement cases. In addition, it has maintained stricter substantive patent examination thus preventing excessive extension of patent terms.

Kenya's patent legal framework

As a member of WTO, Kenya has also adopted minimum standards set by TRIPs in its national IP framework. Under Kenya's legal framework, patent law is protected under the Industrial Property Act (IPA) and administered by the Kenya Industrial Property Institute (KIPI).[43] Among the key functions of KIPI is to administer industrial property rights including patents, industrial designs and trademark,[44] while original jurisdiction to hear patent disputes is vested in the Industrial Property Tribunal. Appeals are heard by the High Court.

The IPA contains public health exemptions in line with TRIPs flexibilities in the form of compulsory licensing and parallel importation. In particular, Section 58(2) provides for parallel importation for genuine goods and section 73 provides that a compulsory licence may be issued only to the extent necessary.[45]

The Judiciary: Kenya and India

Judicial authority in Kenya is established by Article 159 of the Constitution which provides "…that judicial authority is derived from the people and vests, and shall be exercised by Courts and Tribunals established under this Constitution."

The Courts in Kenya in hierarchal order are the Supreme Court, Court of Appeal (COA), High Court, Environment and Land Court (ELC), Employment and Labour Relations Court (ELRC), Magistrates' Courts and the Kadhi's Courts.

Article 169 (1) of the Constitution of Kenya defines subordinate courts under the judiciary to include local tribunals as may be established by an Act of Parliament. The Intellectual Property Tribunal has been established pursuant to this provision and the Industrial Property Act with the mandate to have original jurisdiction to hear patent and other industrial property disputes. The Managing Director of KIPI also has power to make decisions over specific issues relating to industrial property. Appeals from the Tribunal are heard by the High Court. The second appeal is to the Court of Appeal and the final appeal is to the Supreme Court.[46] Like in the US, right of appeal to Kenya's Supreme Court is not automatic and a case must be certified for hearing under the Supreme Court Rules. Decisions of the Supreme Court are final and binding. The Kenyan Supreme Court was established under the Constitution, 2010 as the apex court in Kenya.[47] To date, it has not heard or determined any IP cases.

In India the court system is composed of the Supreme Court, the High Court, District and Village Courts in that order of hierarchy. The Supreme Court is the court of final jurisdiction and its decisions are binding. Judicial authority is derived from the Constitution. The Constitution of India recognises the right to life which provision has been interpreted by the Supreme Court to include right to timely medical treatment.[48]

Role of the Judiciary in Balancing Innovation and Access

The courts in developing countries play a crucial role in enforcing patent rights. As seen in both Kenya and India, the right to health is recognised as a core human right. However the right to IP is equally protected as a property right. Thus courts must adjudicate and resolve IP and related cases in a manner that does hinder innovation nor compromise access to medicines.[49]

Case studies from Kenya and India discussed below reveal how courts and other administrative bodies can assist in improving access to medicines.

Selected Case Studies from India and Kenya

There are various case studies from these two jurisdictions. This section highlights cases that have had a significant impact on the access to medicines question.

Indian case studies

Novartis v. Union of India[50]

The subject of this litigation was pharmaceutical product Glivec (imatinib mesylate) used for cancer treatment and produced by Norvartis International AG,

a Swiss multinational pharmaceutical company. The patent application No. 1602/MAS/1998 was first filed in India on 06/17/1998 by Novartis. Further patent on the modifications was filed in 2005. The claims in the patent application were for "Crystal modification of N-Phenyl-2-Pyrimidineamine derivative, process for its manufacture and its use." In 2005, Cancer Patients Aid, Cipla and others filed an opposition to the patent application. After hearing the opposition, the Controller of Patents and Designs in 2006 rejected the patent application for failure to exhibit inventive step and enhanced efficacy. This led to a protracted seven year court battle. One of the main issues raised in the litigation was interpretation of section 3(d) of the Patent Act and whether modifications of drugs should be patented. Pfizer argued this provision was contrary to the TRIPS Agreement.[51] The Supreme Court upheld the decision of the Patent Office and the Appellate Board which had rejected patent application of the modification of the drug.

Supporters of this decision have argued that the interpretation of section 3(d) is in line with Article 27 of TRIPS which sets minimum standards of patentability for inventions which are novel; involve an inventive step (non-obviousness); and are useful (industrial applicability). The Novartis product herein for which the Company was seeking to patent was a modification of an existing known product for cancer treatment. A lot of policy arguments have been made against patentability of minor modifications especially for pharmaceutical products.[52] This decision sets an important precedent rejecting patentability of modifications of existing drugs. Surprisingly, the same drug has been patented in various patent offices around the world including Kenya.[53] The Novartis decision was significant to the whole world, especially for developing countries which rely on generic medicines produced in India as Gleevec is a highly effective treatment for cancer and if the patent was issued on the modification, it would have extended the term of the patent.

Below is a table from the Intellectual Property Appeal Board showing outcome of recent selected pharmaceutical cases in India.

Table 2: Outcome of recent selected pharmaceutical cases in India

Company	Drug/Disease	Issue	Current outcome
Bayer	Nexavar - kidney cancer	Patent office ordered Bayer to license its drug to Indian firm to produce low cost generic	IPAB rejected Bayer appeal to overturn compulsory licence on 03/04/2013; Further appeal to Mumbai High Court pending
Bayer	Nexavar - kidney cancer	Sued Cipla for patent infringement	Hearing in Dec 2012
Novartis	Glivec – leukemia	India refused to grant patent to Swiss firm in 2006	India Supreme Court rejected Novartis patent appeal on 04/01/2014 after 7 year legal battle.
Roche	Tarceva – cancer	Roche sued Indian companies for patent infringement	Delhi High Court dismissed Roche's patent infringement case in Sept 2012 after 4 year struggle
Roche	Valcyte (AIDS)	Patent office revoked Roche's patent	Appeal pending before IPAB
Gilead	Viread (HIV)	Patent office rejected two patents	Appeal pending

Other Cases

There are several other examples of other pharmaceutical products in which India has implemented the TRIPs flexibilities adopted in its national Patent Act, to prevent excessive patent periods and/or meet public health needs. The relevant provisions include patentable subject matter, or applied the TRIPs flexibilities like compulsory licence. Decisions by the Indian Patent Appeal Board are appealed to the High Court.

Kenyan Case Studies

Pfizer Inc. v. Cosmos Limited[54]

The subject of this litigation was a pharmaceutical product known as azithromycin dehydrate commonly used for treatment of opportunistic diseases associated with HIV/AIDS. It is produced by Pfizer Incorporated, a US based pharmaceutical company. Pfizer sued Cosmos for patent infringement. Cosmos raised two defences. First, it challenged the validity of the patent but this defence was rejected as the Patent was found to be valid. Second, Cosmos relied on parallel importation provision under section 58(2) of the IPA alleging that importation was non-infringing because Pfizer's patent rights had been exhausted. In its decision delivered in 2008, the Tribunal rejected both defences and found Cosmos liable for patent infringement.[55] The Tribunal also issued orders for destruction of the remaining stock of infringing drugs and an order of injunction restraining the respondent from further infringing the patent for the remainder of the patent term which incidentally expired in about 3 months from the date of this particular ruling. The Tribunal held that the rights under section 58(2) were not a blanket provision which a third party could rely on to infringe a valid patent.

Patricia Ochieng & 2 others v. Attorney General & AIDS Law Project[56]

The subject matter of this litigation was a Constitutional petition by persons living with HIV and AIDs (PLWAH) seeking declaratory orders to affirm their fundamental right to life, human dignity and health. The Petition was filed in the High Court at Nairobi, in the Constitutional and Judicial Review Division. At the core of the litigation was interpretation of section 2 of the Anti-Counterfeit Act which defined counterfeiting as:[57]

" means taking the following actions without the authority of the owner of intellectual property right subsisting in Kenya or elsewhere in respect of protected goods—

a. the manufacture, production, packaging, re-packaging, labelling or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods;

b. the manufacture, production or making, whether in Kenya or elsewhere, the subject matter of that intellectual property, or a colorable imitation thereof so that the other goods are calculated to be confused with or to be taken as being the protected goods of the said owner or any goods manufactured, produced or made under his licence;

c. the manufacturing, producing or making of copies, in Kenya or elsewhere, in violation of an author's rights or related rights;

d. in relation to medicine, the deliberate and fraudulent mislabeling of medicine with respect to identity or source, whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging…"

The Petitioners argued that their right to access to affordable generic medicines was in danger due to the ambiguity in this section and sections 32 and 34 which had not specifically distinguished generic drugs from counterfeits. The UN Special Rapporteur on the right to health filed an amicus brief in support of the Petition supporting the Petitioners' argument that the ambiguity in the Act could be misinterpreted to the detriment of the Petitions by limiting access to medicines and by extension, hindering their right to the health.

The Respondent, the Honourable Attorney General of the Republic of Kenya sought dismissal of the case and counter-argued that the statute had no ambiguities; and that generics are clearly distinguishable from counterfeits. He argued there was no need to specifically exempt them in the definition section. In the her Judgment Honourable Lady Justice Mumbi Ngugi, considered relevant provisions of the Industrial Property Act, IPA, the HIV Act, as well as relevant international treaties. The judgment details the socio economic impact of HIV and Kenya's National AIDS strategic plan. In finding in favour of the Petitioners, the Court held that that under Article 43 of the Constitution and other international treaties,[58] Kenyans have the right to the highest attainable standard of health. Further that the failure to distinguish generic medicines from counterfeit drugs, the section was ambiguous and could be subjected to interpretation which could threaten the Petitioners right to life which encompasses right to access affordable HIV medicines including generic drugs. Accordingly, the Court declared section 2 unconstitutional. This case is a landmark case for Kenya as it the first decision in which the High Court has considered IP rights and the right to health; and upheld the right to health, as a basic human and constitutional right.

Comparative Analysis: Balancing Innovation and Access to Medicine in Kenya and India

There are some similarities and some striking differences between Kenya and India in their manner of addressing innovation and access in cases involving pharmaceutical patents.

First, both countries are developing countries. Therefore they share some of the same challenges associated with a countries at developing status such as poverty of a large section of its population. However, there are significant differences between the two countries.[59] India is at an advanced stage of economic development generally. Moreover it has a well-established domestic pharmaceutical industry. In cases involving foreign patents in India, the existence of domestic pharmaceutical interests is often a critical factor in patent enforcement cases since the Indian Government including the Judiciary is keen on protecting and promoting its local industry. The cases discussed in the preceding sections illustrate the consistent policies and strategies adopted in India to prevent extension of patent terms. Kenya, on the other hand lacks a large domestic pharmaceutical industry, and mostly relies on importing drugs.

Second, India has adopted stricter patent legislation and patentability standards. Novartis Glivec drug was rejected by the India's Patent Office and the decision was confirmed by the Supreme Court on the basis of Section 3(d) of India's Patent Act which limits patenting of modifications of known existing substances without sufficient improved efficacy. Kenya on the hand conducts less substantive patent examination in Kenya and accepts patents registered at regional level by the African regional Intellectual Property Organisation (ARIPO). For instance, Novartis Glivec and many other drugs rejected in India are patented in Kenya through ARIPO. In addition, the Indian judiciary largely supports decisions by the Patent Office by passing consistent judgments rejecting excessive pharmaceutical patents. There are much fewer court decisions in Kenya over patent infringement involving pharmaceutical products, thus case law is limited. By comparison, the flexibilities adopted in Kenya were more in line with increasing importation of drugs to deal with the HIV/AIDS crisis under section 58(2) of the IPA which authorises parallel importation or through voluntary licences.

Third, arguably, the Indian Government and its Judiciary have exhibited independence and ability to withstand international pressure and global corporate interests. India has faced a lot of criticism about strategies it has adopted in respect of patenting of pharmaceutical products including the rejection of pharmaceutical products prior to 2005 and currently section 3(d) of the Patent Act. Its independent Judiciary continues to apply the provisions of the Patent Act to balance innovation with access.

Latitude for Courts to Improve Access

Generally, the role of a judiciary in any country is to administer justice according to the law. This requires interpretation of statutory provisions and application of the law to the facts of a particular case. How the law is interpreted ultimately determines the outcome of a case. In addition, both Kenya and India are common law countries. Therefore in principle courts can make law through its judicial decisions. But this occurs only in limited circumstances because IP and particularly patent is highly regulated by virtue of TRIPs.

By virtue of their membership to WTO, most developing countries including India and Kenya have limited room to determine their IP laws to suit national interests since their laws must comply with minimum standards set by TRIPS. As a result of the IP laws passed pursuant to TRIPS obligations, courts in Kenya and India must adhere to TRIPs. The more expansive latitude which existed prior to 2005 has been eroded.[60] Currently, latitude for courts exists only in the form of TRIPs flexibilities that is compulsory licence, parallel importation and patentable subject matter.

As discussed above, India's court system is a good example of a judiciary that has continued to apply existing flexibilities to improve access, and prevent excessive and prolonged patent terms. Kenya may adopt and implement legislation which promote compulsory licensing to avail necessary drugs in the market at reasonable cost. The Industrial Property Act already permits compulsory licensing under certain conditions. If the same is challenged by a patent holder, courts should where possible be reluctant to enforce the patent holders' rights so as to improve access.

It is noteworthy that any existing latitude for courts to promote access does not exist in a total vacuum. It requires the participation of all stakeholders including the legislature, the executive, the patent office and other industry players. In India, the legislature has passed patent laws which can be used by judges to improve access. For instance, the removal of patentability of pharmaceutical products prior to 2005 and the current section 3(d) of India's Patent Act give the courts provisions which can be interpreted to improve access. India's patent office is vigilant in patent application examinations and frequently rejects applications which do not meet the enhanced efficacy requirement set by section 3(d) or other patentability standards. When such decisions are appealed, the courts are also quick to dismiss the appeal thus balancing innovation and improving access.

In addition to the laws and statutes, both national and international, judges are restricted by the doctrine of *stare decisis. Stare decisis* is a Latin maxim which means to "stand by that which is decided." Under this doctrine, courts are required to follow legal precedents set by previous decisions especially that of a superior court.[61] Thus, for example, in Kenya and India, the decisions by the Supreme Court are binding on all other courts within that country. *Stare decisis* plays an important role in ensuring rule of law and predictability in outcome of cases and interpretation of statutes. Accordingly, a latitude a judge has in a patent dispute will also be determined by previous judgments and interpretation of the law by higher courts. In India, the Supreme Court has set good precedents for balancing innovation and access. Kenya's jurisprudence on patent matters is not as well advanced.

Courts should where possible fast track and expeditiously hear and determine cases involving pharmaceutical patents and access to health issues. While all cases in a judicial system are important, cases involving access to medicines fundamentally have a public interest element to them with potential to affect a

large segment of members of society's access to healthcare. Undue delay of such cases may impede access to medicines. Therefore due to the caseload pending in the Kenyan judicial system for instane, initiatives to fast track such cases would aid in expeditious determination of the disputes. As at the reporting year 2014/15, the total number of cases pending in Kenya's judicial system was 612,309.[62] Without concerted efforts to fast tracking access to medicines related cases, these cases may remain pending in the system for a while thereby impeding access.

By improving access to justice generally, through reduction of physical, procedural and technical barriers to justice, the judiciary can vastly improve resolution of related disputes. Patent law is by nature a specialised area of law. The common litigant may not very well understand the intricacies of patent law and may be unlikely to file a claim challenging the legitimacy of a patent granted for minor adjustments such as evergreening, even where it directly affects his right to health. Therefore concerted efforts to improve and simplify court procedures and court filing fees would aid the *pro se* litigants.[63] Various efforts have been adopted by the Kenyan judiciary to improve access to justice. Among them is the restructuring and transition of tribunals under the ambit and management of the judiciary. The Industrial Property Tribunal is one of 15 tribunals which have been transitioned to the judiciary from their parent ministries.[64] Further efforts to improve determination of patent disputes should be implemented by the judiciary.

Conclusion: Lessons for Judges and Magistrates

Whether explicitly stated or not in the various judgments by the courts or decisions by patent offices, which involve pharmaceutical products and processes, there are usually public health policy implications. Strict construction of patent claims and refusal to patent certain products such as modifications without enhanced efficacy, can go a long way in promoting access to medicines or promoting domestic pharmaceutical industries such as India's. To the extent possible, judges should uphold decisions by patent offices especially where those decisions promote access.

First, for a judge to effectively hear and determine a patent case, he should have good knowledge and understanding of IP and particularly national patent law. Specialised advanced training in this area would assist the judge to better grasp the issues. Second, because international IP obligations brought on by WTO and WIPO ultimately affect domestic patent laws, the judge should also keep abreast of international developments on IP. Third, the judge may consider judgments in other jurisdictions as persuasive authority.

While progress has certainly been made towards improving access to medicines generally for developing countries, more can still be done and the judiciary has a big role to play while adjudicating patent and related disputes.

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[2] This inequality has arisen partly because of resource availability for research and development in the richer nations and also their technological capability. However, there are some exception in developing countries like India, Brazil and others which have developed indigenous local pharmaceutical industries which began by focusing on generic medicines.

[3] However, there are regional and international patent treaties which have influence patent norms and registration.

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[6] TRIPS also provides for protection of copyright and other industrial property rights like trademarks, industrial design and geographical indications among others.

[7] Article 28(1) of the TRIPs Agreement.

[8] Accordingly by 2005, even India had to amend its laws to allow patenting of pharmaceutical products. See Mueller, J.M. (2007). The tiger awakens: the tumultuous transformation of India's patent system and the rise of Indian pharmaceutical innovation, *University of Pittsburg Law Review* 68, 491. Retrieved from https://lawreview.law.pitt.edu. DOI https://doi.org/10.5195/lawreview.2007.79.

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[11] Wikipedia, (2014) *Section 301 of the Trade Act of 1974*. Retrieved from http://en.wikipedia.org/wiki/Section_301_of_the_Trade_Act_of_1974).

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[23] A generic drug is an identical copy (bioequivalent) of a brand name drug

[24] Waning, B., Diedrichsen, E., Moon S. (2010) *A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries, Journal of International AIDS Society* . Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2944814/.

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[26] Neglected tropical diseases include some parasitic diseases transmitted by insects (such as Chagas disease; leismaniasis; African trypanosomiasis, commonly known as sleeping sickness); bacterial infections (such as trachoma, Buruli ulcer), others, however, are spread by contaminated water and soil infected with eggs of worms (lymphatic filariasis, commonly known as elephantitis; onchocerciasis, commonly known as river blindness; hookworm).

[27] Vinicio M., Feres C. (2012) Law as identity: the case of drugs for neglected diseases, *US-China Law Review.* Retrieved from https://Heinonline.org.

[28] However, since pharmaceutical products and processes require regulatory approval, the term of protection has been increased in most jurisdictions to cater for the period before approval is granted and the product or process can be safely put on the market. In the US, the term was increased by the Hatch Waxman Act for a period between 5 to 14 years, to compensate patentees for the period lost when seeking regulatory approval from the Food and Drug Administration (FDA). Other countries have similar statutory provisions which extend patent terms.

[29] The practice is also known as stockpiling, layering, life-cycle management or line extensions.

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[35] Use of compulsory licences have certain limitations. First, prior to issuance of a compulsory licence authorization of the patentee must be sought on reasonable commercial terms. However, in event of a national emergency the need for negotiations is waived. Second the scope and use of a compulsory licence must be limited to public noncommercial use; predominantly for the domestic market and shall be non-exclusive

and non-assignable. Third, the patentee shall be paid reasonable compensation. See Article 31 of TRIPS.

[36] African countries like Zimbabwe, Kenya, Mozambique, Zambia and South Africa have in the past issued compulsory licences for production of ARVs to address HIV/AIDS infections in their jurisdictions. See Musungu, S., Oh, C. (2005). *The use of flexibilities in TRIPS by developing countries: can they promote access to medicines, at 8, supra.*

[37]Merges, R., Menell, P., Lemley, M. (2012). *Intellectual property in the new technological age*, Wolters and Kluwer, New York at p. 128.

[38] For instance in the US, patent restoration for pharmaceutical patents is regulated by the Hatch Waxman Act, 1984. Under this Act, patent term can be extended for 5-14 years if the patent was issued after 1984. See Bair, S., (2013). Adjustments, extensions, disclaimers, continuations: when do patent term adjustments make sense? *Capital University Law Review* 41, 445. Retrieved from https://lexisnexis.org.

[39] India has the third largest pharmaceutical industry by volume and considered the 14th largest in terms of value of the industry. In 2010, its estimated value was $10billion, and sales projected to grow to $74billion in 2020. According to Gabble and Kohler, with this robust pharmaceutical industry it may be easy to assume that access to medicines for all has been achieve in India. Surprisingly, this is not the case. Poverty is a significant concern as about 70% live on less than $2 a day and only 5% with access to private health insurance. See Gabble and Kohler *supra* at 2

[40] Mueller, J. (2007). The tiger awakens: the tumultuous transformation of India's patent system and the rise of Indian pharmaceutical innovation, *University of Pittsburg Law Review* 68, 491.

[41] Mueller, J., *Ibid.*

[42] Gabble and Kohler *supra* at 2

[43] KIPI is a Government agency created under an Act of Parliament under the Ministry of Industrialization and Enterprise Development.

[44] See official Kenya Industrial Property Institute website. Retrieved from www.kipi.go.ke.

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[57] The section contained a proviso to the effect that the paragraph did derogate from the existing provisions under the Industrial Property Act.

[58]The relevant treaties which Kenya is a signatory to: are the International Convention on Economic, Social and Cultural Rights, Convention on Elimination on all forms of Discrimination on Women and Convention on the Rights of the Child all provide for the right to health.

[59] Development is measured by indexes like per capita income, gross domestic product (GDP), and human development index (HDI)

[60] Before 2005, developing countries like Kenya and India had the transition period before implementation of TRIPs was required.

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