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Intellectual Property, Access to Medicines and Public Health Issues in Bhutan

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Abstract

The effects of the trade liberalisation process has been felt in Bhutan; even though it is a developing country and one of the smallest markets in the world it has not been able to escape from the inevitable. This is evident from the accession process to the World Trade Organization, which is at an advanced stage. One important key factor in being compliant with the WTO is meeting the minimum standards of Trade-Related Aspects of the Intellectual Property Rights (TRIPS) Agreement. Multiple challenges exist in implementing the standards of the TRIPS Agreement. It has been argued that the effects of WTO-TRIPS compliance will be detrimental to Bhutan's free health care policy, particularly access to medicines in the light of a lack of pharmaceutical industry and manufacturing capacity. The present legislation on intellectual property in Bhutan lacks necessary safeguards and flexibilities in the public health arena; these safeguards are present within the TRIPS Agreement and that is further amplified by the Doha Declaration on TRIPS and Public Health. In order to sustain Bhutan's free health care policy, it is not only imperative to bring its legislation on intellectual property in line with the TRIPS Agreement but also other relevant institutional mechanisms on public health such as drug policy, technical capacity on pharmaceuticals and enforcement which need to be thoroughly examined.

Introduction

Bhutan is one of the Least-Developed Countries (hereafter LDC)[1] in the world nestled in the high Himalayas between the two Asian

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economic giants, India and China.[2] The economy of the country is based on agricultural farming, forestry, tourism and the sale of hydroelectric power, mainly to India. Agriculture provides the main livelihood to more than 79 percent[3] of the population. A cautious planned development in the 1960s[4] opened Bhutan's door to the outside world, after which significant structural changes in the economy have been witnessed.[5] Bhutan's economy continues to be one of the smallest in the world; however in recent years it has rapidly grown: by eight percent in 2005, 14 percent in 2006 and by 22.4 percent in 2007.[6] At present there is increased economic activity, such as establishment of modern trade and a commerce system, infrastructural development, information and communication technologies, health and education etc. It is noteworthy that Bhutan did not embark on modern development purely for economic pursuits, but the development activities are strongly well-balanced with the principles of Gross National Happiness[7] (hereafter GNH). The principle is based on the ideology that the process of economic pursuit should not compromise the elements of social progression, such as culture and traditions and natural environment, which are all strongly associated with the promotion of the well-being of the people.

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1 The United Nations Office of the High Representative for the Least Developed Countries, *List of Least-Developed Countries: Country Profile* (2008) <http://www.unohrlls.org/en/ldc/related/62/> at 4 October 2010.
2 National Statistical Bureau, *Statistical Yearbook of Bhutan* (2009) <http://www.nsb.gov.bt/pub/syb/syb2009.pdf> at 4 October 2010.
3 Ibid.
4 Lily Wangchuk, *Facts about Bhutan: The Land of Thunder Dragon,* (Absolute Bhutan Books, Bhutan: 2008), 28.
5 Gross National Happiness Commission, *Bhutan 2020: A vision for peace, prosperity and happiness* (1999) <http://www.gnhc.gov.bt/publications/pub/Bhutan2020_1.pdf > at 4 October 2010.
6 National Statistics Bureau, Government of Bhutan, *Statistical Yearbook of Bhutan 2009*, 24.
7 Wangchuk, above n 157, 161.

Bhutan's development activities after the 1970s were grounded on the principle of GNH that promises to preserve the cultural values and natural environment focusing on sustainable development and promotion of good governance.[8]

Bhutan is an LDC and also a landlocked country and faces a plethora of challenges in the process of development, such as 'financial, administrative and economic' constraints. In addition, due to its geo-political positions, the modern economic activities that increasingly penetrated the country after the 1960s were viewed as a threat to the country's culture, traditions and natural environment. The philosophy of GNH was instituted at a vital time to protect from the threats of modernisation and the promotion of public health is one of the core components of the GNH principle.[9]

Bhutan has an interesting 'history of health set-up in 1960s' when it began the planned economic development. Human resources were one of the major constraints faced by Bhutan then, and even today, despite rigorous efforts to build capacity, human resource constraints continue to burden the government. In 1960 there were only three medical doctors (two national and one external expatriate) and two nurses who worked in all parts of Bhutan.[10] At that time there were only two hospitals and 11 dispensaries.[11] The 'diseases prevalent then were Malaria, Diarrhoea, Worm Infestations, Tuberculosis (hereafter TB), Goitre and venereal diseases like syphilis and gonorrhoea'.[12] Also there were high 'maternal and child mortality' that were mostly due to

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[8] Ibid.

[9] Gross National Commission of Bhutan, Government of Bhutan, *Tenth Five Year Plan Volume I Document 2008 – 2013* (2009) 17.

[10] Lungten Z. Wangchuk, *States of Bhutan's Health 2008* (2009), Annual Health Bulletin 2009, Ministry of Health, Government of Bhutan, 15.

[11] World Health Organization, *Country Health System Profile: Bhutan* (2007) <http://www.searo.who.int/en/Section313/Section1517_10768.htm> at 4 October 2010.

[12] Wangchuk, above n 15 – 16.

'haemorrhage, prolonged labor and infections'.[13] Despite this fact, Bhutan did have a health care system that was functional, which was managed by the limited number of health professionals.

An examination of the initial health system in Bhutan shows that numerous challenges such as lack of human resources (health professionals), finance and infrastructure were present. Due to the rugged terrain most of the far flung villages and remote parts of the country were virtually inaccessible to the health care services. The state of the population's health was very poor, and the failure to provide timely health care services and the lack of medical personnel was affecting thousands of people. Partly due to these reasons, traditional medicine has retained a 'significant role in the provision of health services' in Bhutan. It is widely practised across the country and even today it is 'provided side by side with modern allopathic health care'. The modernisation of the 'health system and infrastructure commenced in 1960, establishing Basic Health Units (hereafter BHU) in certain places in early 1970s'.14 The actual expansion of infrastructure started only in the 1980s. The health care system today has evolved into a 'fairly efficient system' that has a strong primary health care delivery system as the backbone of the overall system. Presently, the modern health care services are delivered 'through a four-tiered network' comprising of the National Referral Hospital, the Regional Referral Hospitals, District Hospitals and BHUs to 'outreach clinics at the community level'.[15]

Today Bhutan's health system is appreciated by the whole world for its coverage as well as for the effective delivery of its services. A significant improvement in the health indicators have been seen, such as: an increase in life expectancy at birth from 36.1 years in the 1950s

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[13] Ibid.

[14] World Health Organization, *Country Health System Profile: Bhutan* (2007) <http://www.searo.who.int/en/Section313/Section1517_10768.htm> at 4 October 2010.

[15] Ibid.

to 66.1 years at present; a decline in under-five mortality from 108/1000 live births to about 60.1/1000 live births; and a decrease in infant mortality from 185/1000 live births to about 40.1/1000 live births.[16]

The problem that has now arisen as a result of the modernisation process is that the sustainability of the health care system in Bhutan is under enormous threat, predominantly from the intellectual property rights (hereafter IPR) regime. Bhutan enjoys free health care delivery system,[17] mainly due to the fact that majority of people are poor[18] and cannot afford modern medical treatments. They depend on the government for the delivery of medicines and treatments. Bhutan is steadily liberalising its 'trade, industries and financial polices'[19] that call for the adoption of IPRs and compliance with international standards, so as to create a conducive environment for trade and commerce and an influx of investment[20] for internal and external markets. The IPR regime that Bhutan is intending to institute will seriously impact the delivery of the health care system in Bhutan.

This paper is divided into four parts that attempt to discuss the position of Bhutan as an LDC in the areas of IP, access to medicine and Public Health issues. Part I of the paper discusses the state of Bhutan's current health policy and system and investigates policy issues, the current health situation, health and drug policy and institutional linkages. Part II will study Bhutan's current IP laws; in

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16 Wangchuk, above n 16.

17 Bhutan Health Management and Information System, Ministry of Health, Government of Bhutan (2010) *Annual Health Bulletin 2010.*

18 National Statistical Bureau, *Statistical Yearbook of Bhutan* (2009) <http://www.nsb.gov.bt/pub/syb/syb2009.pdf> at 5 October 2010.

19 Ibid 198.

20 Nima Tshering Tamang, 'Low FDI ceilings to attract more investors' *Bhutan Times* (Thimphu) May 30, 2010 <http://www.bhutantimes.bt/index.php?option=com_content&task=view&id=2002&Itemid=5> at 5 October 2010.

particular, it will attempt to establish linkages between public health and access to medicines and other safeguards. Part III of the paper will examine Bhutan's position under the Doha Declaration (hereafter Declaration) on Trade-Related Aspects of Intellectual Property (hereafter TRIPS) Agreement and Public Health. Part IV will examine Bhutan's draft Industrial Property Bill that will discuss the flexibilities required on access to medicines and public health issues and other safeguards in order to accelerate accession to the World Trade Organization (hereafter WTO). Finally, the paper will conclude with recommendations and a review of the situation in the context of the above.

Health Care System in Bhutan

Provision of free basic health care services that are 'publicly financed' has been one of the principles of State policy in Bhutan for more than four decades of planned socio-economic development.[21] The State views the health care system as fundamental to upholding the principles of GNH. It is evident that the practice of providing health care in Bhutan was not an overnight decision but one that has been carefully executed from the early 1960s to the present. The foundations of the health care system are based on the fact that the majority of the population whose livelihood is agriculture and subsistence farming are poor and are located in remote parts of the country. The situation is worsened by the lack of infrastructure such as roads and hospitals, and the low rate of literacy.22 They obstruct the dissemination of information on health, nutrition and sanitation and hygiene. In order to improve the well-being of the people, improvement in their health is

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[21] Tshering Dhendup, *The Present Free Health System and its continuity,* Annual Health Bulletin 2010, Ministry of Health, Government of Bhutan, i, iv.
[22] Bhutan's current literacy rate is 52.8 percent according to Human Development Report 2009 by the United Nations Development Programme. See <http://hdrstats.undp.org/en/countries/country_fact_sheets/cty_fs_BTN.html>.

vital. This cannot be possible without improvement in the infrastructure such as hospitals, medical equipment, supply of medicines and drugs and development of human resources.

Article 9 section 21 of the Bhutanese Constitution states that:

> The State shall provide free access to basic public health services in both modern and traditional medicines.[23]

The inclusion of free access to public health services in the Constitution highlights the importance the government has placed on health and on the overall health policy of the country.

Efforts to establish modern medical facilities began in 1962 and presently the Ministry of Health has a widespread 'network of health facilities across the country, covering 90 percent of the population'.[24] In the early phase of this development, institutional health facilities that were earlier 'concentrated in the urban centres are shifted to rural areas' increasing the access to more and more places. The most important change to the health system today is promoting wider coverage, especially to the remote parts of the country. In these places, an adequate number of BHUs are established providing treatment on 'ailments and advice on preventive measures to avoid the spread of communicable diseases'.[25]

Commendable efforts have been made in terms of prevention of communicable diseases. Bhutan is one of the few countries that has high immunization coverage of more than 90 percent.[26] The prevention efforts saw significant health improvements particularly in the area of disease elimination. Leprosy was eliminated in 1997,

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[23] Bhutanese Constitution, Art 9, s 21.
[24] National Statistical Bureau, Government of Bhutan, *Statistical Yearbook of Bhutan* (2009), ch 2, 34.
[25] Ibid.
[26] Wangchuk, above n 18.

[27]Poliomyelitis in 1984,[28] Iodine Deficiency Disease in 2003.[29] Considerable growth has been observed in terms of infrastructure and human resources. Recent reports record that in 2008 there were 171 national doctors, 567 nursing staff and 1250 other health workers delivering care at 31 hospitals and 174 BHUs.

Analysis of key health indicators from 1984 to 2008, such as maternal mortality rates and morbidity trends, suggest that there has been a significant decrease in the rates of mortality and morbidity. As already stated, one of the driving forces behind the overall improvements in the health status is the result of wider coverage and establishment of necessary infrastructure. In '2000, maternal mortality ratio stood at 255 per 100, 000 live births, a significant decline of 62 percent from the 1984 figure'.[30] A similar trend can be observed in the child health service that has dramatically reduced the infant mortality rate. The infant mortality rate per 1000 live births stood at 102.8 percent in 1984, 70.7 percent in 1994,[31] 60.5 percent in 2000,[32] and 40.1 percent in 2005 and 2009.[33]

A 'shift in the disease dynamics' has occurred and has changed from the most common illnesses being infectious diseases to being chronic diseases such as hypertension, cardiovascular diseases, cancers and diabetes. Other diseases are also common such as cholera, typhoid, measles, blood diseases, and other disorders of the muscular and

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27 Ibid.
28 Ibid.
29 Ibid.
30 Jayendra Sharma, *State of Bhutan's Health 2009* (2010), Annual Health Bulletin, Ministry of Health, Government of Bhutan, 3.
31 Health Division, Ministry of Health and Education, Government of Bhutan, *A Report on National Health Survey 1994* (1996), 18.
32 Department of Health Services, Ministry of Health and Education, Government of Bhutan, *A Report on National Health Survey 2000* (2000), 3.
33 Jayendra, above n 4.

nervous system.[34] It is reported that 'infectious diseases trends have taken challenging shift from curable to incurable like HIV and other viral diseases'[35] in addition to already prevalent diseases like malaria and TB, which are listed as major communicable diseases of the era. There was a total of 1159 reported cases of TB in 2009,[36] of which 30 people died. Although TB prevention programmes were initiated as early as the 1980s, it continues to be prevalent, especially in the remote parts of the country that remain unaware of the prevention programs. The most challenging aspect of TB prevention today is the 'drug resistant strains of TB and TB-HIV co-infections which seriously threaten prevention and control efforts'. Of the 185 reported cases of HIV infection, 11 of them are co-infected with TB.[37]

One of the biggest concerns of the country today is related to the HIV/AIDS threat. The first two cases of HIV infection in Bhutan were detected in 1993.[38]Although the number of people who suffer from HIV/AIDS is at present only 185[39] (prevalence of 0.1 percent), with respect to the size of the population, which is just over half a million, there is an imminent risk of an AIDS epidemic. The steep rise in the number of HIV/AIDS cases is attributed to a number of 'environmental factors such as higher prevalence rates of HIV/AIDS in neighbouring countries, rising level of substance abuse, multiple partners and demographical profile characteristic of young population' (about 43 % are younger than 15).[40] Additionally, the lack of

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[34] Ibid.
[35] Wangchuk, above n 16.
[36] Jayendra, above n 4.
[37] Ibid.
[38] Ministry of Health, Government of Bhutan, *Annual Health Bulletin 2006* (2006), 11.
[39] Tandin Pem, 'Survey reveals poor lab facilities' *Bhutan Observer* (Thimphu) 14 May 2010, <http://www.bhutanobserver.bt/2010/bhutan-news/05/survey-reveals-poor-lab-facilities.html> at 5 October 2010.
[40] Jayendra, above n 4.

awareness of the disease is deteriorating the situation and more and more cases are reported every year.

The government has developed a three-tier AIDS prevention strategy. Firstly, at the peripheral level, health assistants educate the community, train village health workers, counsel patients and refer them for AIDS tests and manage the symptoms. Secondly, at the district level, patients are tested for AIDS along with TB patients and those in the high-risk group. Anti-retroviral (hereafter ARV) treatment monitoring is also done in regional referral hospitals. ARV drugs are given to people with AIDS in an effort to enhance and prolong their life. It is also given to infected mothers in the hope of preventing mother-child transmission. The Multi-Sectoral Task Force [41] that was formed coordinates several activities in the districts for HIV/AIDS, among others. Thirdly, there are also programmes like the National AIDS programme (hereafter NAP) under the Ministry of Health which guides policy formulations in this area.

In a recent health policy discussion, it was stated that:

> HIV/AIDS, tuberculosis and malaria prevalence would be reduced to a level at which it would no longer constitute a public health problem through multi-sectoral and multi-disciplinary approach. Provision of holistic health education in all educational institutions would be promoted through multi-sectoral approach.[42]

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[41] Multi-Sectoral Task Force was formed in 2001 in all 20 districts in Bhutan. The task force consists of people from business community, corporation and regional and sectoral head chaired by the Governor of the district. The task force deals with emerging and re-emerging diseases (particularly awareness creation of HIV/AIDS) and disasters.

[42] Sonam Peldon, 'Policy for better health care facility' *Bhutan Observer* (Thimphu) 26 May 2010, <http://www.bhutanobserver.bt/2010/bhutanesetown/05/policy-for-a-better-healthcare-facility.html> at 5 October 2010.

Due to the urgency of the issue, the government has called for a collective effort across the public sector and private organisations in preventing the spread of the disease. Advocacy on the disease is regularly conducted across the country involving students and teachers, parents, the public and private sector, armed forces, monk groups and the general public. The government maintains absolute confidentiality of the identity of the HIV/AIDS patients for reasons of social stigma, among others.

Key components of the Tenth Five Year Health Development Plan (2008 – 2013)

Bhutan's overall long-term objective of the health system is 'attaining a healthy living standard by the people living within the broader framework of the overall development of the country'.[43] Four important programmes underscore the current Tenth Five Year Development Plan programme of 2008 to 2013: health management and development programme, health promotion and disease prevention and control programme, diagnostic and curative service programme and sustainability, and a regulatory and monitoring programme.[44] Firstly, under the health management and development programme, the focus has been on the overall intensification of HR development and capacity building programme. The programme outlines that during the plan period:

> [A]ccelerated human resource development will be pursued to build the critical pool of clinical personnel required to close the existing human resource gaps through increased scholarships for Bachelor in Medicines program and other medical fields.[45]

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[43] Gross National Commission of Bhutan, Government of Bhutan, *Tenth Five Year Plan Volume I Document 2008 – 2013* (2009).
[44] Gross National Happiness Commission of Bhutan, Government of Bhutan, *Tenth Five Year Plan Volume II Document 2008 – 2013* (2009), 173, 204.
[45] Ibid 174.

The present situation indicates an acute shortage of man-power, predominantly skilled medical personnel in the health ministry. In view of the lack of medical colleges in the country, students are sent outside the country to pursue higher education in medicine and other medical fields. As the medical field is a highly specialised field, fewer than thirty candidates[46] from the whole country get selected for the Bachelor of Medicine Programme every year. From a long-term perspective, it is believed that the shortage in medical personnel will be gradually addressed through such programmes; in the short-term, the shortage is being addressed through temporary recruitment from neighbouring countries.[47]Recently the government announced the establishment of the first ever medical college in the country. The college, which is tentatively expected to open in July 2011,[48] will see the introduction of a Bachelor of Medicine and a nursing programme, among others. The establishment of the college is 'expected to help address the country's current shortage of medical staff and additional need of 180 medical specialists, 896 medical officers, 45 assistant clinical officers, 872 nurses and 722 technicians required by 2013'.[49]

Secondly, under the health promotion and disease prevention and control programme, it has been identified that there are still major

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[46] Department of Adult and Higher Education, Ministry of Education, *Undergraduate Scholarship Program 2010* (2010) <http://www.education.gov.bt/annuoncements/Announcement-2008-09.pdf> at 5 October 2010.

[47] Gross National Happiness Commission of Bhutan, Government of Bhutan, *Tenth Five Year Plan Volume II Document 2008 – 2013* (2009), 174.

[48] Dipika Chhetri, 'Foundation laid for future of medicine in Bhutan' *Kuensel* (Thimphu, Bhutan) 1 May 2010 <http://www.kuenselonline.com/2010/modules.php?name=News&file=article&sid=15335> at 5 October 2010.

[49] Rinzin Wangchuk, '2011 deadline for Ngultrum 250 million project' *Kuensel* (Thimphu, Bhutan) 6 January 2008 <http://www.kuenselonline.com/2010/modules.php?name=News&file=article&sid=14410> at 5 October 2010.

challenges regarding disease prevention in the country. The major cause of morbidity continues to be Acute Respiratory Infection (hereafter ARI) and Diarrheal Diseases.[50]These diseases are a result of the poor supply of drinking water and sanitation facilities across the country.[51]Another key focus of the programme is the prevention of TB and HIV/AIDS, which continue to remain rampant in the country despite vigorous control and awareness programmes.

The plan also highlights an intensification of preventive programmes for other diseases and health issues such as maternal and adolescent health, reproductive health, cervical cancer and several other communicable diseases such as malaria, dengue and leishmaniasis which are of significant public health concern.[52] A growing concern today, however, is the increase in 'lifestyle related diseases' such as hypertension, asthma, cancer, chronic liver disease, heart disease and obesity that is proving not only costly, but at the same time induces the need to revamp major health services in the country.

Thirdly, the diagnostic and curative service programme incorporates the capacity to treat and handle threats from recent epidemics like Severe Acute Respiratory Syndrome (hereafter SARS), avian flu and Swine Flu. In light of such threats, it is proposed to construct bio-safety levels and a public health laboratory[53] in the capital Thimphu, that will conduct laboratory testing and institute necessary prevention strategies whenever the situation demands. However, most of the other hospitals across the country are poorly equipped lacking facilities such as X-ray machines, blood laboratory and ultrasound equipment to deal with major 'crisis situations'. Thus, owing to factors such as lack of necessary facilities, inadequacies in personnel and 'highly rugged terrain

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[50] Gross National Happiness Commission of Bhutan, Government of Bhutan, *Tenth Five Year Plan Volume II Document 2008 – 2013* (2009), 176.
[51] Ibid.
[52] Ibid.
[53] Ibid 181.

and harsh climatic conditions', telemedicine is considered as a viable alternative to enhance access to high quality diagnoses and care'.[54]

Finally, a significant amount of expenditure in the health sector is incurred from the purchase of vaccines and drugs. The sustainability of the health care delivery sector in light of the rising cost of vaccines and drugs depends on a secure financial system. Bhutan is a donor-driven country that depends immensely on external funds and assistance from international groups such as the World Health Organization (hereafter WHO), the United Nations Development Programme (hereafter UNDP) and bilateral countries.[55] Therefore, in order to 'establish provisioning of health services on a sustainable footing, the government established the Bhutan Health Trust Fund' in 1997[56] to 'finance the purchase of essential drugs and vaccines'. The foundation of the Trust Fund is on the basis that by 'ensuring the sustainable financing of essential drugs and vaccines through the Trust, the government can concentrate allocation of national budget to other 'key elements of public health care' such as human resource development and strengthening infrastructure.

Drug Procurement, Regulation and Policy

As noted already, in the absence of a pharmaceutical industry and manufacturing capacity, one of the priority concerns for Bhutan in the health sector is financing and procurement of drugs and medicines. In view of this constraint a systematic approach on procurement of drugs and medicines is imperative to ensure quality and an adequate and timely supply for the market in Bhutan. The health ministry outlines that in order to 'safeguard and protect human and animal health against

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54 Ibid.

55 Annual Health Conference, Ministry of Health, Government of Bhutan, *New era in Health and the challenges ahead* (2009), 3, 58.

56 Bhutan Health Trust Fund, Ministry of Health, Government of Bhutan, *Bhutan Health Trust Fund* (2010) <http://bhutanfound.org/?p=955> at 6 October 2010.

harm resulting from poor quality of medicinal products' the control and regulations of such products in the market is very important. Under the health ministry, the Drug Regulatory Authority[57] (hereafter DRA) was established in 2004 to regulate medicinal products and enforcement of the *Medicines Act 2003*.

The preamble of the *Medicines Act 2003* states that:

> [w]hereas it is necessary to control the sales of medicinal products in the effort of ensuring safety, efficacy and quality at affordable prices the government will adopt necessary regulatory mechanisms to monitor licensed premises, strengthen laws relating to medicinal products and control the manufacture, storage, transportation, sale, import and export of such products. [58]

On this basis, the *National Drug Policy 2007* guides the 'pharmaceutical sector including traditional medicines, in the areas of quality assurance and regulations, supply management, manufacture, monitoring and evaluation'.[59] It was observed that, until 1986, numerous problems confronted the drug supply system such as 'availability, quality, irrational prescription and high cost', and it was these issues that triggered the institution of the Essential Drugs Programme (hereafter EDP) in 1987. The Policy mentions that 'essential drugs shall be procured to ensure cost effectiveness and sustainability'[60] through a central procurement system whose objective 'shall be to procure acceptable quality drugs at reasonable prices'.[61]

From the financing aspect, despite acute financial constraint the government continues to allocate adequate financial provision to

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[57] Drug Regulatory Authority, Ministry of Health, Government of Bhutan, *Background* <http://www.health.gov.bt/dra.php> at 6 October 2010.
[58] Bhutan Medicines Act 2003, Preamble.
[59] National Drug Policy 2007.
[60] Ibid s 3.
[61] Ibid s 3 (2).

ensure procurement and supply of drugs in an effort to 'reduce dependency on donor'[62] agencies. To overcome this constraint, alternative financing sources[63] are explored from time to time. In addition, to ensure the drug supply chain, local manufacture of pharmaceuticals[64] is encouraged through exemption of all forms of taxes.[65] The fact that drugs and medicines are costly, 'projection of drug cost from time to time and developing appropriate models for costing'[66] is strongly highlighted.

Accordingly, the drug policy on IPR and pharmaceuticals states the in order to 'safeguard the national interest concerning public health and ensure access to pharmaceuticals' the cost and benefit analysis of international treaties and conventions related to trade needs to be carefully studied. The policy underscores the importance of keeping the public health and access to pharmaceuticals at the forefront when undertaking any 'bilateral or international treaties related to trade in health'.[67] Particularly on TRIPS, the policy highlights that the government will take 'advantage of all the flexibilities and safeguards within the TRIPS Agreement for the promotion of public health and ensuring access to pharmaceuticals'.[68] In order to do this, the collaboration of Ministry of Health and Ministry of Economic Affairs including other relevant agencies in the area of IPR is important in instituting a legal framework that is conducive to access to essential drugs and incorporating flexibilities such as Compulsory Licensing (hereafter CL) and Parallel Importation[69] (hereafter PI), which are discussed in the later part of this paper.

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[62] Ibid s 6.
[63] Ibid s 6 (3).
[64] Ibid s 9.
[65] Ibid s 6 (4).
[66] Ibid s 6 (5).
[67] Ibid s 13.
[68] Ibid s 13 (1).
[69] Ibid s 13 (2).

Intellectual Property and Public Health in Bhutan

Prior to 2001, IP laws were not a part of the national legal system in Bhutan. IP is a fairly recent concept in Bhutan that continues to face a series of challenges and constraints at the implementation level. The situation of IP can be best described as being in its nascent stages, with major institutional stakeholders and the general public only beginning to understand the importance of it. There is generally inadequate awareness among major players such as the public sector, creative industries and enforcement agencies[70] due to which the progress in terms of its development has been rather slow.[71] As mentioned elsewhere in the paper, despite planned economic development activities as early as the 1960s, [72] very little progress has been made in areas that are intrinsic to IP. It has been viewed that a lack of industrial-based activities and a lack of Research and Development (hereafter R&D) has strongly held up the progress in IP.[73]

The law on IP dates back to as early as 1995, when the World Intellectual Property Organization (hereafter WIPO) fielded an expert mission to initiate formulation of legislation for Bhutan. Subsequently, the *Industrial Property Regulations 1997* was adopted, which was seen as an initial step taken by the government in recognising the importance of IPR in the country. Under these regulations, facilities for registration

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[70] Jigme Wangchuk, 'Copyright Law enforcement seeks criminal sanction' *Bhutan Observer* (Thimphu), June 26, 2010 <http://www.bhutanobserver.bt/2010/bhutan-news/06/copyright-law-enforcement-seeks-criminal-sanction.html> at August 25, 2010.

[71] Nima Wangdi, 'Getting a law to work' *Kuensel* (Thimphu), June 28, 1010 <http://www.kuenselonline.com/modules.php?name=News&file=article&sid=15900> at 6 October, 2010.

[72] Lily Wangchuk, *Facts about Bhutan-the Land of Thunder Dragon* (Absolute Bhutan Books, Thimphu, Bhutan: 2008) 28.

[73] Tashi Dorji, 'What's in a Brand name?' *Kuensel* (Thimphu), October 22, 2006 <http://www.kuenselonline.com/modules.php?name=News&file=article&sid=7615> at 7 October, 2010.

of trademarks were commenced in May 1997, while enforcement of other parts of the regulations pertaining to patents and industrial designs were deferred until such time as the facilities could be instituted. It was only in 2001, when the *Industrial Property Act 2001* and the *Copyright Act 2001* were enacted, that IP laws became a part of Bhutan's national legal system.[74] However even today, most of the provisions of the Acts are still not operational,[75] owing largely to a lack of technical capacity, trained personnel and lack of necessary infrastructure. Due to its late inception, the law in this area is still struggling to gain importance in trade and commerce, research and the national legal system.

The importance of IPR protection is strongly highlighted in the recently endorsed *Economic Development Policy 2010*. It stresses the need to 'initiate, promote and support R&D' that has a resultant effect on IP. The Policy highlights the need to formulate a comprehensive legislative framework for recognition and protection of IPR[76] in the country. Besides opening up a host of business opportunities as a potential Foreign Direct Investment (hereafter FDI) under the policy, IPR protection is understood as an indisputable component of instituting an enabling environment for private sector development and FDI.[77]

In order to understand the present situation on IP better, a brief mention of its legislative and administrative framework should be made. IP is governed by the *Industrial Property Act 2001* that covers industrial property titles such as patents, industrial designs, trademark,

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[74] National Assembly of Bhutan, *Record of list of Acts passed* <http://www.nab.gov.bt/legislation.php?start=60&slno=31&dept=act> at 7 October, 2010.

[75] Intellectual Property Division, Ministry of Economic Affairs, Government of Bhutan, *About us*: *The Intellectual Property Division,*< http://www.ipbhutan.gov.bt/aboutus.aspx> at 7 October, 2010.

[76] Economic Development Policy 2010, ss 7.1.12, 7.10.4

[77] Foreign Direct Investment Policy 2010, s 4.7.

trade secrets and unfair competition, while copyright is governed by the *Copyright Act 2001*. Trademark protection was commenced as early as 1997 and it continues to be one of the most active Registries. About ninety nine percent of the trademark applications are filed from overseas through the Madrid System[78], and the rest are national and local applications. In spite of its early start, trademark popularity among businesses is only beginning to pick up. The figure of local trademark application is suggestive of its popularity in the business and commerce area.

One of the major challenges faced currently by Bhutan is the operationalisation of patents although a number of studies were undertaken, studying both the advantages and disadvantages of initiating patents, especially in the context of LDC; to date patents still remain under study. Bhutan as a technologically backward country perceived that the implications, benefits and consequences of patent initiation will have to be studied further. At present, with the level of technical capacity and constraints in financial and administrative resources, it is viewed that Bhutan is not yet ready to commence patents. Subsequently a feasibility study was carried out that recommended the draft Industrial Property Bill (hereafter draft Bill).

The *Industrial Property Act 2001* does not contain any specific provision on pharmaceutical patents; however, a number of possible situations are outlined that allows government intervention; these are situations concerning exploitation of patents such as in a national emergency or other circumstances of extreme urgency[79] determined by the government. Section 15 of the Act concerns the CL of patents. It begins by mentioning that the public interest in 'nutrition and health'[80]

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[78] *Madrid Agreement Concerning International Registration of Marks,* opened for signature 14 April 1891 (entered into force 1 December 1995).
[79] Industrial Property Act 2001, s 15 (6) (b).
[80] Ibid s 15 (1) (i).

among other issues, and in the case of anti-competitive behaviours,[81] the government can authorise exploitation of the patent 'even without the agreement of the owner'[82]; however, the exploitation of the patent will be limited to the 'purpose for which it was authorized'[83] and subject to the 'payment to the said owner of an adequate remuneration'.[84] The section also points out that in case of inability to obtain or refusal to grant a contractual license for exploitation of patent from the owner on 'reasonable commercial terms and conditions and within a reasonable time',[85] the government can authorise a designated third party to exploit the patent exclusively for the 'supply of the market in Bhutan'.[86]

Apart from Section 15 of the Act covering CL, there are no other provisions that safeguard public health and access to medicines such as PI and exhaustion of IP rights. In view of this, Bhutan is in the process of amending its patent legislation to incorporate necessary flexibilities that are present under the TRIPS Agreement and the Declaration on TRIPS and Public Health, which is discussed in the following part of the paper.

Bhutan's position under the Doha Declaration on TRIPS Agreement and Public Health

It is clear from the above discussion that, in the immediate time frame, Bhutan is not in a position to operationalise patents due to significant constraints in technical capacity and resources among others. Bhutan is only beginning to emerge in areas that are intrinsic to patent generation, such as R&D, increased industrial base activities and FDI;

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81 Ibid s 15 (1) (ii).
82 Ibid s 15 (1) (ii).
83 Ibid s 15 (1) (ii).
84 Ibid s 15 (1) (ii).
85 Ibid s 15 (6) (a).
86 Industrial Property Act 2001, s 15 (7).

however, it is uncertain how soon the process is going to make an impact on patent culture. Even in other areas such as Trademark and Industrial Designs, national and local applications form an insignificant portion of the total applications.

The Doha Declaration on the TRIPS Agreement and Public Health is of significant relevance to Bhutan because of numerous reasons that are discussed below. In 2001, WTO members adopted a special Ministerial Declaration at the WTO Ministerial Conference in Doha, Qatar, to clarify 'ambiguities between the need for government to apply the principles of public health and the terms of the TRIPS Agreement'.[87] The declaration was passed due to the growing concern that 'patent rules might restrict access to affordable medicines[88] for populations in developing countries and LDCs'[89] in their efforts to control diseases of public health importance such as HIV, TB and malaria.[90] A closer look at the Declaration shows the affirmation[91] of the WTO members to implement appropriate measures to protect public health, through full use of the safeguard provisions of the TRIPS Agreement, in order to enhance access to medicines for poor countries.[92] All but two aspects of the TRIPS Agreement under the Declaration are referred that are particularly relevant to LDCs; one:

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87 World Health Organization, 'Access to Medicines' (2003) 19 [3] *WHO Drug Information* 236, 241.

88 Stiglitz, E, Joseph, *Economic Foundations of Intellectual Property Rights* (2007) Duke University School of Law <www.law.duke.edu/shell/cite.pl?57+Duke+L.+J.+1693+pdf> at 10 October 2010.

89 World Health Organization, above n 236, 241.

90 Phillippe Cullet, 'Amended Patents Act and Access to Medicines after Doha' (2002) 37 (24) *Economic and Political Weekly* 2278.

91 Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001 by the Fourth WTO Ministerial Conference, Doha, Qatar <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> Paragraph 4 (b) at 10 October 2010.

92 Phillippe, above n 1.

CL[93] and, two: the 'freedom to establish the regime of exhaustion of IP rights' and PI.[94]

Compulsory Licenses

The TRIPS Agreement enables a 'competent government authority to license the use of patented invention to a third party or government agency without the consent of the patent-holder'.[95]The grant of CL is subject to certain conditions, such as consideration of 'individual merits, need to demonstrate prior negotiations with the patent holder for a voluntary license and the payment of adequate remuneration to the patent holder'.[96]In order to address a 'national emergency or other circumstances of extreme urgency' additional requirements such as the 'need to obtain a voluntary license' from the patent holder is waived. [97] This process is further hastened by the Declaration through grant of the 'freedom to Members to stipulate the grounds upon which such licenses are granted'. Recognising this need of poor countries with respect to public health, such flexibilities are enshrined in the TRIPS Agreement which is further amplified by the Declaration.[98]

The granting of CL is mainly to regulate the 'exclusive rights conferred by patents' that restrict abusive use of patents. Particularly in the case of health, the rationale of CL is to prevent a situation whereby 'the

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93 Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001 by the Fourth WTO Ministerial Conference, Doha, Qatar <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> Paragraph 5 (b) at 10 October 2010.

94 Ibid Paragraph 5 (d)

95 Trade-Related Aspects of Intellectual Property Rights Agreement, Art 31

96 Ibid, Art 31 ss (a) – (j).

97 Ibid, Art 31 s (b)

98 Declaration on the TRIPS and Public Health, above n Paragraph 4.

existence of patent in a protected medicine is not available to the public due to non-health related factors.'[99]

Parallel Importation

PI is the 'importation without the consent of the patent-holder of a patented product marketed in another country either by the patent holder or with the patent holder's consent'.[100] The underlying principle of exhaustion states that:

> Once patent holders or any party authorized by him or her, have sold a patented product, they cannot prohibit the subsequent resale of that product since their rights in respect of that market have been exhausted by the act of selling the product.[101]

To illustrate the above, Bayer's ciprofloxacin (500mg), an anti-biotic, cost 740 US dollars in Mozambique. In India, Bayer sells the same drug for 15 US dollars, due to local generic competition. Considering the cost is cheaper in India, Mozambique can import the drug from India without Bayer's consent.[102]

Article 6 of the TRIPS Agreement on exhaustion states:

> For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be

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[99] Phillippe, above n 1.
[100] World Health Organization, The Doha Declaration on the TRIPS Agreement and Public Health (2010) <http://www.who.int/medicines/areas/policy/doha_declaration/en/> at 10 October 2010.
[101] Ibid.
[102] World Health Organization, *Parallel Imports* (2010) <http://www.who.int/trade/glossary/story070/en/> at 10 October 2010.

> used to address the issue of the exhaustion of intellectual property rights.[103]

Further, the Declaration reaffirms this right by stating that each 'member is free to establish its own regime for such exhaustion without challenge'.

Both CL and PI are important tools for Bhutan in the public health area. Under the present *Industrial Property Act 2001,* CL is strongly incorporated. There is, however, no provision on PI. These tools allow the government to address the public health issues, particularly access to drugs through 'exploitation of patents' and 'import of lower priced patented drugs' as illustrated. It is observed that pharmaceutical products (even the same pharmaceutical products) are sold at different prices in different markets; therefore, the rationale for PI is to enable the import of lower priced pharmaceuticals from a foreign market to supply the domestic market. Bhutan can incorporate CL and PI in its legislation to enable exploitation of patents and import of lower priced pharmaceuticals from neighbouring countries, considering the constraints in pharmaceutical patents and lack of manufacturing capacity.[104] A very important aspect of this flexibility to be noted, particularly regarding CL, is the fact that Bhutan lacks manufacturing capacity in the pharmaceutical sector. In the immediate future, if Bhutan initiates patents, there will be fewer patent applications and thus CL in this respect will be irrelevant as it allows supply for the domestic market only.[105] On the other hand, PI will benefit Bhutan through the import of lower priced pharmaceuticals from countries like India.[106] In order to comply with the TRIPS Agreement, and

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[103] Trade-Related Aspects of Intellectual Property Rights Agreement, Art 6.
[104] Declaration on the TRIPS and Public Health, above n Paragraph 6.
[105] Alan O. Skyes, 'TRIPS, Pharmaceuticals, Developing Countries, and the Doha Declaration Solution' (2002) 3 (1) *Chicago Journal of International Law* 47.
[106] Tandin Dorji, 'Effect of TRIPS on Pricing, Affordability and Access to Essential Medicines in Bhutan (2007) Vol. 16, *Journal of Bhutan Studies,* 128.

subsequently incorporating the necessary flexibilities especially pharmaceutical patents, LDCs are allowed transitional period until January 1, 2016.[107]

Amendments to the *Industrial Property Act 2001* and the draft Industrial Property Bill

The *Industrial Property Act 2001* lacks a number of provisions, such as flexibilities on the use of CL and PI and on pharmaceutical patents and enforcement measures, among others. In order to incorporate such provisions, Bhutan is currently in the process of amending its patent and IP legislation. This part of the paper will discuss the draft Bill and pertinent provisions that endeavour to incorporate the flexibilities and create a conducive environment for promotion, as well as protection of public health in the country.

The draft Bill begins by defining matters that are excluded from patent protection and this includes pharmaceuticals until January 1, 2016.[108]As mentioned already, protection of pharmaceuticals will not only be tedious, considering the complex technicalities and examination process, but also unnecessary because the number of applications foreseen is virtually zero. Realistically, the protection of pharmaceuticals will go a long way both in terms of technical capacity of the IP Office as well as local manufacturing capacity. The grant of pharmaceuticals in light of the public health crisis will deter access to drugs and medicines, as the pharmaceuticals become increasingly expensive as a result of patents.

< http://www.bhutanstudies.org.bt/main/pub_detail.php?pubid=104> at 10 October 2010.

[107] Declaration on the TRIPS and Public Health, above n Paragraph 7.

[108] Draft Industrial Property Bill, s 1 (ix).

As required by the TRIPS Agreement, the draft Bill grants both product and process patents.[109] The impact of this provision is largely going to be in the import and making of 'generic drugs' imported from India and other neighbouring countries.[110] As a matter of fact, Bhutan continues to benefit from the import of generic drugs from India since patented drugs are highly expensive and thus, granting of product patents will not only impede the import of generic drugs, but also prevent any local pharmaceutical companies, from utilising the processes to make products or generic drugs.[111]

A comprehensive provision relating to PI is proposed under the draft Bill. Section 11 (4) of the draft Bill states:

> The rights under the patent shall not extend to acts in respect of articles which have been put on the market in any territory or country by the owner of the patent or with his or her consent, consequently exhausting the patent owner's rights.[112]

The draft Bill empowers the Minister concerned to declare patent rights exhaustion 'authorizing' a designated party or government agency to 'import the patented product from another territory when that product is not available or available in the territory of Bhutan with unreasonably low quality standards or in a quantity that is not sufficient to meet the local demand or at prices' that are abusive.[113] The import of drugs is important to maintain the continuity of delivery of health services and particularly during a 'national emergency or circumstances of extreme urgency' when drugs and vaccines are required in a timely and sufficient manner, this provision will expedite the process of drugs and vaccines acquisition.

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[109] Ibid, ss 11 (2) (a) and (b).
[110] Dorji, above n 131.
[111] Ibid 134.
[112] Draft Industrial Property Bill, s 11 (4).
[113] Ibid ss 11 (5) (i) – (ii).

CL is further submitted under the draft Bill reasoning the requirement of CL as a measure to safeguard public health and other social objectives. This is precisely the subject matter under Paragraph 6 of the Declaration as already discussed. The Declaration acknowledged 'that countries with insufficient or no manufacturing capacity may find it difficult to make use of [CL] and thus allows import or export of products produced under [CL] provided that both countries of import and export have issued such licenses'[114] upon duly notifying the TRIPS Council.

Section 13 of the draft Bill charts out an in-depth provision on CL. The purpose of CL rests on the basis that in situations such as 'nutrition, health or other vital sectors of the national economy'[115], anti-competitive behaviour[116],abusive exercise of exclusive rights by the patent-holder[117] or when the 'invention is not available in sufficient quantities or quality' at reasonable prices in Bhutan 'either through manufacture in Bhutan or through importation'[118], the draft Bill empowers the Minister concerned, 'even without the agreement' of the patent holder, to exploit the invention by a government agency or a designated third party.

The conditions on the grant of CL that are already discussed are present under the draft bill. They are: a CL is to be considered on its individual merits; the exploitation of the invention shall be limited to the purpose for which it was licensed and a CL shall be subject to the payment to the said owner of an adequate remuneration.[119] Specifically, the grant of CL with respect to pharmaceutical products or a process

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[114] HEPS, Uganda Coalition for Health Promotion and Social Development, *TRIPS flexibilities in Patent laws* (June 2008), 17.
[115] Draft Industrial Property Bill, s 13 (1) (a) (i).
[116] Ibid s 13 (1) (a) (ii).
[117] Ibid, s 13 (1) (a) (iii).
[118] Ibid, s 13 (1) (a) (iv).
[119] Ibid s 13.

when other alternative process of making the same is not known or not available,[120] takes into account the Decision of the General Council of the WTO (hereafter the Decision) of August 30, 2003.[121]This Decision is precisely the implementation of Paragraph 6 of the Declaration, stating that 'member countries having insufficient or no manufacturing capacity in the pharmaceutical sector may choose to grant CL'. The Decision is the result of the instructions set out under the Declaration, where it creates a conducive environment to LDCs in making use of CL to import pharmaceutical products[122] from a developed country, after both notify the TRIPS Council of the intention to use the CL. The exploitation of such an invention is predominantly for the 'supply of the market in Bhutan', and particularly if it concerns pharmaceutical products, the grant of CL is to enable import of pharmaceuticals from a foreign country in accordance with the Decision.

In terms of 'national emergency or other circumstances of extreme urgency or cases of public non-commercial use', the need to obtain a voluntary license is waived which is coherent with the Declaration.[123] The granting of CL whatsoever will not restrict or prevent the patent's owner from exploiting the invention and the owner will be entitled to cross-license[124] and the CL will be a non-exclusive license.[125]

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120 Ibid s 13 (b).

121 Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the General Council on 30 August 2003 at <http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm> at 11 October 2010.

122 Ibid.

123 Draft Industrial Property Bill, ss 13 (5) (a) – (b).

124 Ibid ss 9 (a) – (b).

125 Ibid s 5.

Enforcement and Border Measurement of IP

Enforcement of IP in Bhutan is a serious problem. The *Industrial Property Act 2001* sparingly covers the enforcement of IP[126] and border measures empowering Courts[127] and Customs[128] in the process of infringement[129] and enforcement of the IP law. There is not a single provision detailing how the police will correlate its role in the enforcement of IP under the Act. Not listing the roles of the police under the Act is a serious impediment for enforcement of IP. On several occasions, the police expressed that IP cases are not dealt with by them directly. In a recent media report, it was quoted that one of the reasons of ineffective enforcement is lack of familiarity of 'police personnel with the provisions of the industry property and copyright infringement Act and other related laws and there is lack of training for the police in the field of intellectual property'.[130]

The role of Customs is crucial, especially in preventing and identifying pirated and counterfeit goods at the border level. Once the goods have entered the country, customs officials are still entitled to search and seize the goods. Further, the customs law mentions the authority to seize,[131] restrict and prohibit[132] suspected and illegal goods that are 'imported, exported or sold without prescribed documents, permit or pass'.[133]

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126 Copyright Act 2001, Pt IV.
127 Industrial Property Act 2001, ss 16, 23, 29.
128 Copyright Act 2001, Pt IV s 28 (3).
129 Industrial Property Act 2001, s 41.
130 Meto Dema, „The thieves and the authors", *Bhutan Observer,* 4 February 2010, 11 <http://www.bhutanobserver.bt/2010/featured-stories/02/the-thieves-and-the-authors.html> at 12 October 2010.
131 Sales Tax, Customs and Excise Act 2000, s 7.2.
132 Ibid s 8.1.
133 Ibid.

According to Ugyen Dorji from UC Associates, who is working on formulation of an enforcement framework on copyright:

> [T]he main reasons for ineffective copyright enforcement were lack of training for the police, the Bhutanese judicial system being slow, time-consuming and burdensome, lack of trained intellectual property prosecutors and judges trained in the field of intellectual property rights, and lack of public awareness.[134]

The enforcement framework is particularly raised by the Creative Industry Sector, as piracy is becoming rampant not only inside the country but also at the borders.[135] Enforcement is a critical component of the overall IP development, affecting not only the Creative Industry sector but also other sectors such as health and education, technology, economy and the R&D sector. The enforcement mechanism is important to regulate as well as ensure safety and quality and to authenticate the import of pharmaceuticals inside the country.

Part III of the TRIPS Agreement covers enforcement of IP. Article 41 states that:

> Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements.[136]

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[134] Meto Dema, 'Copyright lack public awareness', *Bhutan Observer* (Thimphu), January 15, 2010 <http://www.bhutanobserver.bt/2010/bhutan-news/01/copyright-lack-public-awareness.html> at 12 October 2010.
[135] Kinga Dema & Gyalsten K Dorji, 'The issue is on other foot', *Kuensel* (Thimphu), January 20, 2010 <http://www.kuenselonline.com/modules.php?name=News&file=article&sid=14525> at 12 October 2010.
[136] Trade-Related Aspects of Intellectual Property Agreement, Art 41.

Accordingly, the draft Bill proposes a separate chapter on enforcement of IPRs, containing comprehensive measures such as infringement proceedings, provisional measures, evidence and burden of proof, damages and other remedies, border measures by Court and Customs and criminal procedures. In all of these measures, the basis is first instituting an effective enforcement regime that caters to promotion of IP in the country and secondly, as a broader concept, prevents entry of illegal goods that may have a negative effect on public interest issues such as health and nutrition.

Conclusion

Bhutan's position regarding the implementation of an IPR regime that allows undeterred access to medicine and addresses public health issues will depend on three key elements. Firstly, having discussed the flexibilities that are present within the TRIPS and subsequently amplified by the Declaration, it is of paramount importance to effectively utilise those flexibilities that will impact the overall health care system in Bhutan. Recognising the special needs of the country, in light of numerous constraints such as inadequate technical competencies, lack of pharmaceuticals and manufacturing capacity and financial and administrative constraints etc. the present draft Bill adequately incorporates the necessary flexibilities to safeguard public health interest. Primarily, the CL and PI in view of the above constraints, create the necessary system and channels through which public health interests such as 'exploitation of patents' and 'importation of drugs' are addressed. Additionally, other measures such as 'limitation on the exclusive rights conferred by patents' also endeavour to help address public health issues.

Secondly, in order to effectively implement IPRs, it is highly essential to put in place a workable enforcement regime. For this purpose, relevant institutional stakeholders have to be proactively involved from time to time in matters that affect the enforcement of IP in the country and beyond. A multi-sectoral approach involving stakeholders from health and education, agriculture, science and information technology

and creative industries, in addition to enforcement agencies *viz.* court, customs, polices and trade and commerce, should coordinate in areas of IP. The enforcement of IP eventually impacts issues that are critical to public health, such as counterfeit drugs, infringement of patents to produce low quality drugs and vaccines and unauthenticated generics that will undermine the state of public health.

Finally, in order to expedite the accession process to WTO,[137] as in the past, several WTO working groups were organised that discussed WTO and TRIPS among others. TRIPS contains the minimum standards on IP that a WTO member should put in place. Presently, the legislative framework covering IP in Bhutan is inadequate and lacks pertinent provisions on several other IP titles, enforcement mechanisms and also safeguards that are present within the TRIPS framework on access to medicines and public health. The discussions on WTO and TRIPS triggered amendments to the *Industrial Property Act 2001* and the draft Bill has been proposed, addressing access to medicines and public health issues among others. While accession to WTO is imperative on account of trade liberalisation and the foreseen benefits resulting from membership, basic standards on IP, including an enforcement mechanism and the necessary safeguards on public health, are packaged under the proposed draft Bill.

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