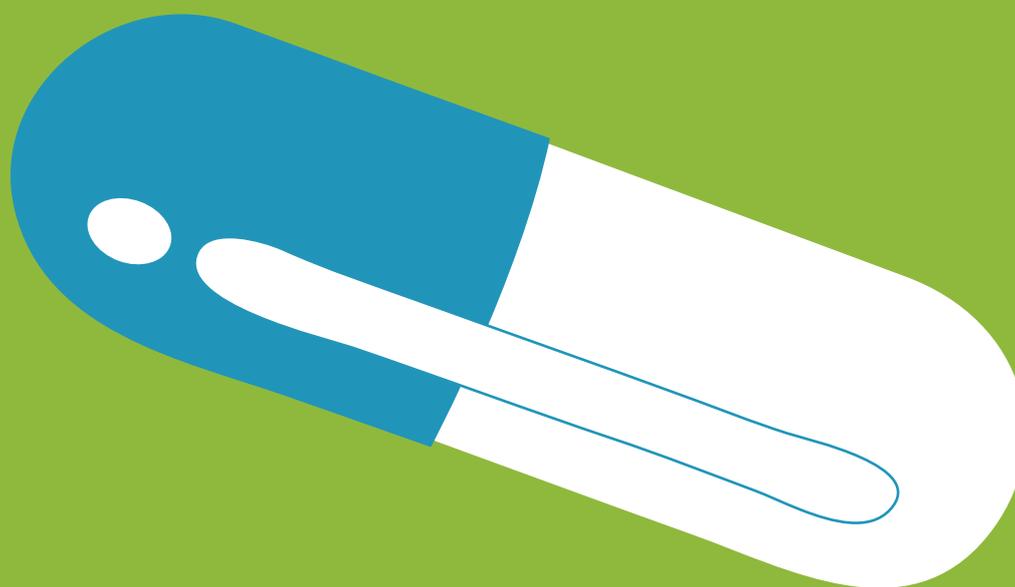




*Empowered lives.
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INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO AFFORDABLE ARVS IN CHINA



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INTRODUCTION

The paper attempts to document the recent developments, opportunities and challenges in intellectual property rights and access to affordable medicines in China. The structure of the paper is as follows. Firstly, the paper starts with the epidemiological situations on HIV and hepatitis B in China (section A) and briefly describes the national response to the problem of access to antiretrovirals (ARVs) (section B). Secondly, it analyzes the situation of local production and exports of finished ARVs and active pharmaceutical ingredients (APIs) (section C). Thirdly, the importance of flexibilities allowed under the Agreement on Trade Related Aspects of Intellectual Property Rights ('TRIPS Agreement') is highlighted (section D), followed by an analysis of such flexibilities in China's intellectual property regime (section E). Finally, the role of civil society in improving prevention and treatment of HIV and access to ARVs is discussed.

A PREVALENCE OF HIV IN CHINA

A.1 How large is the epidemic?

The first case of HIV in the People's Republic of China was reported in 1985. According to the *2012 China AIDS Response Progress Report* by the Ministry of Health, by the end of 2011, the cumulative reported number of people living with HIV (PLHIV) was about 445,000 cases (up from 230,643 cases at the end of 2007). Of these 174,000 were AIDS cases. The number of cumulative AIDS-related deaths was reported to be 93,000.¹

Case reporting data shows that from 2007 to 2011, the number of reported HIV and AIDS cases (including people living with HIV who have developed AIDS) has increased each year, with the figures for each year standing at 48,161, 60,081, 68,249, 82,437 and 92,940 respectively. The numbers of newly diagnosed cases and deaths also increased each year, with the figures standing at 10,742, 14,509, 20,056, 34,188 and 39,183, as well as 5,544, 9,748, 12,287, 18,987 and 21,234 respectively.²

In recent years, the proportion of reported cases accounted for by homosexual and heterosexual transmission has increased year on year. The proportion of cases resulting from sexual transmission increased from 33.1 percent in 2006 to 76.3 percent in 2011. The proportion arising from homosexual transmission increased from 2.5 percent in 2006 to 13.7 percent in 2011³.

Epidemic estimates show that at the end of 2011, the estimated number of PLHIV in China stood at 780,000 people. Of these, 28.6 percent were women. There were 154,000 cases of AIDS among the total estimation and the overall prevalence stood at 0.058 percent. The estimated number of new infections in 2011 was 48,000 and the estimated number of deaths was 28,000. Of the 780,000 people estimated to be living with HIV, 46.5 percent were infected through heterosexual transmission, 17.4 percent through homosexual transmission, 28.4 percent through injecting drug use, 6.6 percent were former blood donors or transfusion recipients, and 1.1 percent were infected through mother-to-child transmission⁴.

1 UNAIDS, 2012 AIDS Response Country Progress Report: <http://www.unaids.org/en/dataanalysis/monitoringcountryprogress/progressreports/2012countries/>

2 Ibid.

3 Ibid.

4 Ibid.

PLHIV account for 0.058 percent (0.046-0.070 percent) of the total population making China still a low-prevalence country. However the epidemic is severe in some areas. At the end of December 2011, 31 provinces (or autonomous regions, municipalities) had reported HIV cases. 93.2 percent (2,885 of 3,095) of counties (or districts) had reported HIV cases. Variations in reported numbers of cases were quite significant between provinces. The six provinces with the highest number of reported HIV cases (from highest number: Yunnan, Guangxi, Sichuan, Henan, Xinjiang, Guangdong) accounted for 75.5 percent of the total number of reported cases nationwide. The seven provinces with the fewest reported cases of HIV (Tibet, Qinghai, Ningxia, Inner Mongolia, Gansu, Tianjin, Hainan) accounted for 1.2 percent of the total number of reported cases nationwide. The 20 counties (or districts, cities) with the highest number of reported cases of HIV were all located within Yunnan, Guangxi, Xinjiang, Henan and Sichuan.⁵

The *2012 China AIDS Response Progress Report* describes China's HIV epidemic as exhibiting five major characteristics: i) national prevalence remains low, but the epidemic is severe in some areas; ii) the number of PLHIV continues to increase, but new infections have been contained at a low level; iii) there is gradual progression of HIV to AIDS resulting in an increase of the AIDS-related deaths; iv) sexual transmission, particularly among men who have sex with men, is the primary mode of transmission, and continues to increase; v) China's epidemics are diverse and evolving.

One of the major challenges that emerged in this context is the high cost of antiretroviral medicines (ARVs), the bulk of which continues to be imported today, due significantly to patent protection granted to foreign manufacturers. As discussed below, today there is the dichotomy of China being the world supplier of active pharmaceutical ingredients for ARVs, without a corresponding production of generic ARVs for its citizens and millions of patients in other developing countries.

Interface between HIV and tuberculosis (TB)

HIV and TB are so closely connected that they are often referred to as co-epidemics or dual epidemics. There is growing concern that successes in battling TB are being undermined and may even be negated by co-infection of HIV and TB, as well as increasing resistance to TB drugs. People living with HIV are 21-34 times more likely to develop TB in a given year than HIV-negative people. TB is a leading killer of people living with HIV, causing one quarter of all deaths. In 2010 and 2011, the proportions of people estimated to be co-infected with HIV and TB who received combined treatment for HIV and TB stood at 44.8 percent and 35.6 percent respectively.⁶

China was one of the 22 countries with the highest TB burden as identified by the WHO in 2008. China, however, has made dramatic progress in TB control. Between 1990 and 2010, the TB death rate in the country fell by almost 80 percent and the total number of people ill with TB dropped by half.⁷ It also has the largest DOTS (Directly Observed Treatment, Short-course) programme, a key element of World Health Organization (WHO) Stop TB Strategy⁸, in the world. There was a National TB Control Programme (2001-2010) under which the government increased spending and strengthened capacity to deal with the disease. Free diagnosis and drugs have been provided for all active pulmonary TB cases. The new National TB Control Programme (2011-2015) further acknowledges the challenges with the increasing epidemic trend of multi-drug resistance TB (MDR-TB) and sets the goal of expanding the treatment and control on MDR-TB.

Treatment under DOTS involves a 6-month course of drugs to be taken under supervision every other day. The China programme obtained drugs on the international market at competitive

5 Ibid.

6 See footnote 2.

7 <http://www.who.int/mediacentre/factsheets/fs104/en/index.html> (March 2012)

8 See <http://www.who.int/tb/strategy/en/> (last visited on December 5th 2012)

prices – about US\$20 for a 6-month course of drugs (at 2001 prices). Supplies were centralized, and treatment was free.⁹ When the pilot phase ended in mid-2001, the government continued and expanded the DOTS programme to have 100 percent coverage in the country.

Challenges still remain. According to the Ministry of Health (MOH) of China, there was a need for stronger government commitment to further increase financial resources and the number and quality of TB staff¹⁰. The DOTS implementation quality should also be improved. Importantly the National TB Control Programme needs to be expanded to include the migrant population people with MDR-TB and people living with TB/HIV.¹¹ To address this and strengthen the response towards TB and HIV co-infection, the 'China Tuberculosis and HIV Co-infection Response Work Framework' and 'National Tuberculosis and HIV Co-infection Response Work Implementation Plan' were developed.

The same concerns on affordable access created by patents apply to the essential drugs for the treatment of HIV and TB. This is particularly so for second-line TB drugs as drug resistance develops and spreads. The affordable cost of first-line drugs was part of the reason for the success of TB control in the first phase.

ARVs for chronic hepatitis B

According to an epidemiological study conducted in 2006 by MOH, there were 93 million people in China who are hepatitis B carriers.¹² Hepatitis B in China poses a serious public health problem. Each year over a million hepatitis B infections are reported. Hepatitis B is estimated to account for 280,000 deaths annually in China.¹³

In 1992 China implemented the WHO recommendation and included hepatitis B in its vaccination programme. Yet, the coverage of hepatitis B vaccination was low especially in poor and remote areas because families had to pay the cost. In 2005 hepatitis B was designated as one of the four high priority diseases for control in the country and the provision of free Expanded Programme on Immunization (EPI) vaccines to infants was put in place under the new immunization regulation.

China's current 5-year Program of Plan of Action on Health (2011-2015) sets the goal on hepatitis B prevention and control as to reduce the HBsAg¹⁴ carrier rate among the general population to less than 6.5 percent by the end of 2015.

The cost of routine vaccination is high and where universal immunization is a government policy as in China, it constitutes a significant expenditure in the public health budget. According to the WHO, "In the mid-1990s, vaccines to provide 'basic' coverage for tuberculosis, polio, diphtheria, tetanus, pertussis, and measles cost about US\$1 per child. Inclusion of vaccines for hepatitis B and Haemophilus influenzae type b (Hib), raises the vaccine cost alone to US\$7-13 per child (not including administration and injection equipment) in the developing world. When vaccine administration is included, the costs amount to between US\$20-40 per child. It has become a significant challenge for low-income countries and international health agencies to find ways to

9 WHO, China Halves TB Deaths through DOTS (2001): <http://www.who.int/inf-new/tuber2.htm>

10 Bureau of Disease Prevention and Control, Ministry of Health, "Prevention and Control of Major Diseases in China", presentation made at the International Symposium on TRIPS and Public health, Beijing, 10 June 2008.

11 Ibid.

12 See <http://www.moh.gov.cn/publicfiles/business/htmlfiles/wsb/pxwfb/200804/33253.htm>, last visited on December 6, 2012

13 See <http://www.gavi Alliance.org/country/china/documents/proposals/proposal-for-nvs---hep-b-ins-support--china/>, last visited on December 7, 2012

14 HBsAg (surface antigen of the HBV) is a protein antigen produced by the virus and it indicates current hepatitis B infection.

introduce more highly-priced vaccines such as those for hepatitis B and Hib, which can greatly increase the costs of national immunization programmes. With many new vaccines expected to be available in the near future, issues of financing and financial sustainability will become ever more important”¹⁵

The WHO published an important report in 1996 on the state of the world’s vaccines and immunization which highlighted the cost of new vaccines:

“At today’s prices, for example, it costs no more than US\$1 for the original six EPI vaccines (at UNICEF-discounted prices), and another US\$14 for programme costs (laboratories, transport, the cold chain, personnel and research) to fully immunize a child.

However, development of a second generation hepatitis B vaccine in 1986 – the world’s first genetically engineered vaccine – signalled that the days of cheap vaccines were over. Initially marketed at US\$150 for three doses – 150 times the cost of the original six EPI vaccines combined (at UNICEF-discounted prices) – by 1994 this vaccine alone accounted for almost a third of the turnover in the global vaccine market. Even at the discounted prices being offered to UNICEF, the cost of a course of hepatitis B vaccination is higher than a course of the original six EPI vaccines”¹⁶

The high prices are related to patents over new vaccines and this factor will feature each time a much-needed vaccine enters the market.

Meanwhile, treatment of chronic hepatitis B continues to be widely needed in China. Chronic hepatitis B in some patients is treated with the drugs interferon or lamivudine (3TC). However, according to the WHO, interferon or lamivudine therapy costs thousands of dollars and will never be available to most patients in developing countries.¹⁷

In terms of treatment, lamivudine (3TC) is an important drug that is central for both HIV and hepatitis B. It is the main drug used in the treatment of AIDS, which is also the principal antiviral drug in the treatment of hepatitis B.

Due to an ‘administrative protection’¹⁸ accorded to GSK for 3TC that expired only in October 2006 followed by a claim by the company that one of its existing process patents prevents any production or import of generic 3TC, this essential drug remains very expensive. For the same reason, there has been no domestic production or import of some fixed dose combination ARVs. The patent finally expired in April 2011. A more detailed discussion is in Section B below.

While the national AIDS treatment programme can buy and receive international donations to provide free ART, there is no equivalent provision of free drugs for hepatitis B patients. Civil society organizations report that a large number of poor hepatitis B virus carriers are forced to give up effective treatment due to lack of access to 3TC.

In the case of donated 3TC for ART, supply has been reported to be inconsistent – insufficient stocks and shortages in a number of treatment centres were reported in 2007 – raising fundamental questions over the sustainable supply of affordable ARVs.

In early 2008, CSOs and patient groups from the AIDS and hepatitis B communities decided to cooperate to undertake joint advocacy activities and raise public attention on their common

15 WHO, Immunization against diseases of public health importance (2005): <http://www.who.int/mediacentre/factsheets/fs288/en/index.html>

16 WHO, State of the World’s vaccines and immunization (1996): <http://www.unicef.org/newsline/vpressr.htm>

17 <http://www.who.int/mediacentre/factsheets/fs204/en/> (August 2008)

18 Prior to the availability of product patents in China, there was ‘administrative protection’ that provided market exclusivity for originator drugs. This is discussed in Section B of this paper.

plight. Since 2011 the China Access to Medicines Research Group has consolidated its activities and is working to provide significant research and policy contributions to government and civil society efforts to increase access to ARVs (see Section F below).

B NATIONAL RESPONSE TO HIV AND ACCESS TO ARVS

The national HIV response is led by the Ministry of Health, the State Council AIDS Working Committee Office (SCAWCO) and the National Center for AIDS/STD Prevention and Control (NCAIDS)¹⁹. China Centre for Diseases Control provides technical support.

Increasing national commitment to HIV prevention and control efforts has been demonstrated in recent years by improving policymaking and multi-sectoral and societal participation in the AIDS response. In April 2004, the government established SCAWCO, a multi-sectoral body responsible for formulating the national HIV/AIDS policy that is headed by the Vice-Premier and includes 22 vice-ministers and 7 provincial vice-governors. A National Plan for HIV/AIDS Prevention and Control for 1998–2010 was launched in 1998, and the China Plan of Action for Containment and Control of HIV/AIDS (2001–2005) was launched in 2001²⁰.

The China AIDS Response (China CARES) Project was initiated in 2002 to provide comprehensive prevention, treatment and care programme, including antiretroviral therapy.

In 2005, the Ministry of Health and the NCAIDS supported the development of provincial plans for scaling up antiretroviral therapy. Each province now has its own plan for preventing and controlling HIV and AIDS.

In 2006 the State Council strengthened the AIDS policy framework by issuing the *Regulations on AIDS Prevention and Control* and the *Five Year Action Plan for Reducing and Preventing the Spread of AIDS (2006-2010)*.

In 2006-2007 moves were made to strengthen coordination and integration across sectors to plan and implement HIV awareness and prevention campaigns and similar activities. Mass organizations, civil society organizations and business enterprises were targeted to be actively involved in the national response to AIDS. Their range of involvement has become broader in its scope and depth. The number of community-based organizations is increasing and becoming an indispensable force in the national response to the epidemic.²¹

Overall, though, China has stepped up its response to the HIV epidemic in recent years, as seen in part from the *China Action Plan for HIV/AIDS Prevention and Control (2006-2010)*. By 2007 there were 4,293 voluntary counselling and testing (VCT) stations established nationwide. Of these, 803 were VCT clinics in hospitals, accounting for 19.1 per cent. Free HIV testing is available at these sites across all 31 provinces, autonomous regions and municipalities, and more than 40,000 patients were receiving antiretroviral treatment at the end of 2007. However, research at that time

19 Ref. <http://www.chinaids.org.cn>

20 These plans were supplemented by technical guidelines on managing sexually transmitted infections, managing people living with HIV, interventions in vulnerable populations, HIV testing and HIV surveillance.

21 A Joint Assessment of HIV/AIDS Prevention, Treatment and Care in China (2007), jointly prepared by the State Council AIDS Working Committee Office and the UN Theme Group on AIDS in China (December 2007): <http://www.chinaids.org.cn/n443289/n443292/appendix/2008111111551.pdf> The first Joint Assessment was published in 2004.

suggested that the response would benefit considerably from stronger coordination between and across relevant agencies and actors, and from a more concerted focus on most-at-risk groups.²²

A national network to monitor drug resistance was set up. Three nationwide surveys on drug resistant HIV strains have been completed (as of 2008). At the same time, pilot sentinel surveillance of drug resistant was initiated to detect early warning of drug resistance. The monitoring results suggested that approximately 17 percent of PLHIV on ART develop drug resistance.²³

In 2010, China's Global Fund supported AIDS Programme was effectively integrated with China's AIDS response plan and funding. The aim of this integration was to ensure that efforts were combined, promoting joint response work. However, as a result of frequent changes and uncertainty with Global Fund policies pertaining to programme management and funding usage, the implementation of China's response plans was negatively impacted. In particular, in May 2011, the Global Fund suddenly suspended fund disbursement and significantly cut budgets, resulting in a temporary suspension of China's AIDS response work. This impacted on the achievement of 2011 national response objectives, and had a very large negative impact on China's AIDS response.²⁴

The *China Action Plan to Prevent and Control HIV/AIDS (2011-2015)* builds on the achievements and experiences of the previous five-year plan and increasing access to affordable medicines (in particular designated ARVs) via domestic production is explicitly included (see section C.3 below).

UN agencies (especially WHO, UNDP, UNICEF, UNAIDS) have been and continue to be actively involved in supporting and supplementing the government's efforts. International NGOs such as Médecins Sans Frontières and the Clinton Foundation also provided treatment support as well as technical inputs for treatment and care guidelines until the late 2000s.

B.1 Overview of China's antiretroviral therapy

In 2003 the State Council developed the 'Four Free, One Care' policy which provides the following:

- Free antiretroviral drugs to people living with HIV who are rural residents or people with financial difficulties living in urban areas;
- Free voluntary counselling and testing;
- Free drugs to pregnant women living with HIV to prevent mother-to-child transmission and HIV testing of newborn babies;
- Free schooling for children orphaned by HIV; and
- Care and economic assistance to families affected by HIV.

The 2004 Joint Assessment of HIV/AIDS Prevention, Treatment and Care in China, jointly prepared by the State Council AIDS Working Committee Office and the UN Theme Group on AIDS in China reported that the provision of affordable and accessible ARV therapy that patients can tolerate and doctors can readily supervise was a key challenge.

22 Gill B, Huang Y, Lu X (2007) Demography of HIV/AIDS in China: a report of the task force on HIV/AIDS. Washington, Centre for Strategic and International Studies. http://www.csis.org/component/option,com_csis_pubs/task/view/id,3977/type,1/ - cited in UNAIDS/WHO, Asia – AIDS epidemic update (2007).

23 Ibid.

24 See footnote 2.

Expanding access to free ART under the 'Four Free, One Care' policy has thus been a priority, with coverage extended to more areas around the country in recent years. Standardized ART was strengthened, the national drug resistance monitoring system was established and a pilot second-line drug trial was launched in 2007. Comprehensive treatment models, prevention of opportunistic infection treatment and traditional Chinese medicine treatment were under exploration, while care and support have been further intensified.²⁵

While continuing to implement the 'Four Free, One Care' policy to this day, the *State Council Notice on Further Strengthening the AIDS Response* was issued at the end of 2010 setting out new policy measures focusing on the 'Five Expands, Six Strengthens' approach. 'Five Expands' means to expand information, education and communication activities, surveillance and testing, PMTCT, comprehensive interventions, and coverage of ART. 'Six Strengthens' means to strengthen blood safety management, health insurance, care and support, rights protections, organizational leadership and strengthening of response teams.²⁶

In 2010-2011, follow-up and management of PLHIV has been strengthened and follow-up interventions, CD4 testing, and other areas of work have become regularized. In 2011, China issued the *National Free Antiretroviral Treatment Handbook*, revising criteria for initiation of treatment, prioritizing testing for drug resistance, in order to manage switching of drug regimens. At the end of 2011, a total of 3,142 facilities providing ART were in place nationwide, located in 2,082 counties (or districts) within 31 provinces (and autonomous regions, municipalities).²⁷

In 2011 the total number of people ever receiving and currently receiving treatment increased from 81,739 and 65,481 respectively in 2009 to 155,530 and 126,448. Of these the total number of children under 15 ever receiving antiretroviral treatment was 2,788, and the number currently receiving treatment 2,322. 18,703 adults and 216 children are currently receiving second line treatment. The proportion of reported adults and children meeting treatment criteria who were receiving ART treatment increased from 67.2 percent in 2010 to 76.1 percent in 2011 and the proportion remaining alive and on treatment after 12 months increased from 82.3 percent in 2009 to 86.9 percent in 2011. Building on the 'Four Free, One Care' policy, China issued the *Guidance Regarding Strengthening Protection for Orphans* in 2010, creating an initial basic welfare, treatment, recovery, education, employment and accommodation protection mechanism.²⁸

ARV treatment regimen

The first-line regimen of zidovudine (or stavudine) + lamivudine + nevirapine is provided free of charge through the National Free Antiretroviral Therapy Programme. Limited amounts of combinations of zidovudine + lamivudine (Combivir) and of efavirenz are also available within the National Free Antiretroviral Therapy Programme. Prophylaxis to prevent mother-to-child transmission consists of zidovudine from 28 weeks and during labour and a single dose of nevirapine for the mother at the beginning of labour and to the infant within 72 hours of birth.

In 2011, China revised the *National Free Antiretroviral Medication Handbook*. The new edition contains revised guidelines on treatment initiation times, stipulating that all patients with CD4+T cell counts lower than 350/mm³ should receive treatment. Patients with CD4+T cell counts of 350-500/mm³ who meet certain criteria were also recommended to receive treatment. All pregnant women and PLHIV within serodiscordant households were recommended to initiate treatment, regardless of their clinical phase, as defined by the WHO, or CD4+T cell count.²⁹

²⁵ See footnote 18.

²⁶ See footnote 2.

²⁷ Ibid.

²⁸ Ibid.

²⁹ Ibid.

Tenofovir (TDF) also appeared for the first time in the treatment handbook, recommended together with ziduvodine as a first line treatment medication, reducing issues around side effects and reducing the number of pills which need to be taken.³⁰

In 2010, drug resistance testing was first provided for patients for whom treatment had failed. A National ART Resistance Working Team was also established, and the *HIV Antiretroviral Treatment Drug Resistance Work Framework (2010-2015)* was issued. During 2010-2011, HIV drug resistance testing was rolled out, in order to assist with changes in treatment regimens. Work was also carried out on HIV drug resistance epidemiological monitoring, and capacity building and quality control among drug resistance testing laboratories. Analysis of drug resistance shows that drug resistance amongst patients exhibiting virological failure has increased, and that the issue of drug resistance requires additional attention. At the end of 2011, 18,703 adults and 216 children were using second line treatment regimens.³¹

While the inclusion of TDF for first line treatment was welcomed by the health community and CSOs, the prohibitive price of this patented medicine is a major obstacle for access.

As the number of paediatric cases increased, some paediatric drugs have been included in the plan for domestic production.³² Given this important policy decision, it would be very important to ensure that intellectual property rights will not be an obstacle to the production of paediatric ARVs.

B.2 Obstacles to affordable access

In 2008 there were 17 ARVs registered for marketing in China, of which 10 were imported, one was domestic and the remaining six were either imported or domestically manufactured/formulated.³³ In 2011 the number of registered ARVs has increased and there is more joint venture manufacturing/formulation by foreign and domestic companies. However, the ARV market is still dominated by foreign pharmaceutical companies: GSK, Bristol-Myers Squibb, Roche, Abbott Laboratories and Boehringer-Ingelheim.

Table 1 below sets out the various categories of drugs that are registered by the China State Food and Drug Administration (SFDA). The table also indicates the formulations that are registered by domestic suppliers, joint ventures and for imports.

All of the approved second-line originator ARVs are imported, as there is no domestic production. Lopinavir/ritonavir (brand name Kaletra by Abbott Laboratories) was registered first but not marketed for a while. The thermal stable formulation (LPV/r 200mg/50mg, brand name: Aluvia) that does not require refrigeration and is thus crucial for use in developing countries such as China, was approved by the SFDA on 15 November, 2007 for a period of 5 years. Abbott was slow in applying for registration, evoking criticism from those involved in treatment and care.

³⁰ Ibid.

³¹ Ibid.

³² See footnote 18.

³³ SFDA Department of Drug Registration, "HIV drug approval, registration and production", presentation made at the International Symposium on TRIPS and Public Health, Beijing, 10 June 2008.

Table 1: Drugs for HIV and AIDS registered in China (as of September 2011)

NRTI	NNRTIs	NtRTI	PIs	FIs	Entry inhibitor	Integrase inhibitor	Compound preparations
Zidovudine (Domestic & Joint Venture(JV): tablet, capsule, oral solution, injection; Import: tablet, capsule, syrup)	Nevirapine (Domestic & JV: tablet, capsule; Import: tablet, oral suspension)	Tenofovir Disoproxil Fumarate (Import: tablet (Viread))	Saquinavir (Domestic: capsule; Import: tablet, capsule (Invirase), soft capsule (Fortovase))	Enfuvirtide (Import: injection (Fuzeon))	Maraviroc (Import: tablet (Celsentri))	Raltegravir (Import: tablet (Isentress))	Zidovudine+Lamivudine (Domestic: tablet; MNC (GSK) JV: tablet; Import: tablet (Combivir))
Lamivudine (Domestic & MNC JV: tablet, capsule; Import: tablet, oral solution (Epivir))	Efavirenz (Import: tablet, (Stocrin))		Indinavir sulfate (Domestic & JV: tablet, capsule; Import: capsule (Crixivan))				
Didanosine (Domestic: tablet, granule, capsule; Import: capsule (Videx EC))	Etravirine (Import: tablet (Intelence))		Ritonavir (JV: oral liquid; Import: tablet, soft capsule, oral liquid (Norvir))				Lopinavir+Ritonavir (Import: tablet (Aluvia), oral solution, soft capsule (Kaletra,))
Stavudine (Domestic & JV: tablet, powder, capsule; Import: capsule (Zerit))			Nelfinavir (Import: tablet (Viracept))				
Abacavir: Import: tablet, oral solution (Ziagen))			Darunavir (Import: tablet (Prezista))				Abacavir sulfate+Lamivudine+Zidovudine (Import: tablet (Trizivir))
Emtricitabine (Domestic: tablet, capsule)							

Source: State Food and Drug Administration

Tenofovir is currently registered. Gilead Sciences did not file for registration until 2007, and this delay was also criticized by international NGOs with treatment programmes in China as well as the HIV community. TDF is also patented with two known challenges filed by domestic manufacturers currently under consideration by the State Intellectual Property Office.

In early 2012 Gilead signed an agreement with MOH to donate 180,000 bottles of TDF for 12 months of treatment for 15,000 people. Such donations do not ensure predictability of supply, and is a factor undermining more sustainable options, such as compulsory licensing for domestic production.

As with other developing countries, China faces a number of problems in accessing affordable ARVs. The MOH in 2008 already identified the following major challenges and difficulties³⁴:

- Pressure from the increase in the number of people receiving ART and the extension of treatment periods;
- Though domestically produced ARVs are available at low prices, the quality is poor and the drugs are not effective. There is also shortage of domestically produced new drugs, such as second-line ARVs. These factors result in a lack of sufficient range of ARVs and reduce the flexibility of the treatment regimen;
- Imported ARVs are of good quality and effective but the prices are high, thus increasing treatment costs;
- Some ARVs are not registered in China and cannot be imported, resulting in a full dependency on donations (such as paediatric ARVs) and affecting the sustainability of supplies.

In addition, there have been significant delays in the registration in China of ARVs that were available elsewhere. There seems to be a pattern where the originator does not apply or delays in applying for product registration by the SFDA, and when there is registration approved the company does not market the ARV concerned.

B.2.1 Patents and high prices restrict ARV choice

The choice of ARV regimens in China is restricted and this is primarily due to patents on some essential first-line, such as TDF and most of the second-line ARVs.

In 2006, the international medical humanitarian group Médecins Sans Frontières (MSF) conducted a study on major ARVs entitled 'Prices Paid vs. Prices Announced: Examining Prices of Antiretrovirals (ARVs) in China'.³⁵ Actual prices paid by MSF in China for its projects in Guangxi and Hubei provinces in July 2006 were collected. Those prices were compared to international prices gathered in the 9th edition of MSF's "Untangling the Web of price reductions" (July 2006). The study showed the large difference between international offers and prices paid by MSF in China, for first-line, second-line and paediatric ARVs.

Table 2 shows that prices in 2006 for ARVs to be used for treatment in China have been very high. Almost all the essential ARVs listed have been patented thus preventing domestic production and import of generic versions during the patent term. The reasons that explain the less than competitive prices of Chinese generic ARVs are discussed in Section C below.

³⁴ Bureau of Disease Prevention and Control, Ministry of Health, "Prevention and Control of Major Diseases in China", presentation made at the International Symposium on TRIPS and Public health, Beijing, 10 June 2008.

³⁵ All the information on this study is reproduced from the document provided by Médecins sans Frontières (MSF) to TWN.

Table 2: Comparison of ARV prices (2006)*(Unit: US\$, per patient/year)*

	International originator lowest offer	Originator offer in Hong Kong	Originator offer (second category of price)	International lowest generic offer	Chinese lowest generic offer
ABC 300 mg	636	2547	N/A	456	N/A (patent)
ddl 100 mg	310	905	401	190.68	350
ddl 250 mg EC	233	2440	N/A	103	N/A (patent)
ddl 400 mg EC	288	3309	N/A	134	N/A (patent)
IDV 400 mg	400	1037	686	306	438
Lopinavir/ritonavir (heat-stable tablet)	500	5324	2200	1338	N/A (patent)
Nelfinavir 250 mg	683	N/A	1543	986	N/A (patent)
Ritonavir 100 mg	83	3011	N/A	190	N/A (patent)
TDF 300 mg	207	360	N/A	365	N/A (patent application under examination)

Notes:

1. Abacavir (ABC) was registered in China but not marketed. Its patent was in force at the time of the survey.
2. ddl 100 mg is not patented, registered but at the time of the survey was not in stock.
3. ddl EC (enteric coated formulation) was patented, registered but not marketed (planned for January 2007).
4. Lopinavir/ritonavir was patented; the old formulation was registered but not marketed while the new thermal stable formulation was not registered (finally registration was applied for and obtained on 15 November 2007). Extensive price negotiations took place between Abbot Laboratories and the Chinese Government to have supplies at US\$1,100 per person per year.
5. Nelfinavir and ritonavir were both patented, registered but not marketed.
6. TDF patent application and registration are under consideration at the time of the survey.

Source: Médecins Sans Frontières (2006)

The MSF study revealed that in 2006, the less expensive first line regimen (d4T+3TC+NVP) costed five times more in China than the lowest international generic offer. This was due to GSK's monopoly on 3TC in China, which blocked access to the generic first-line fixed-dose combination (FDC) widely used in many other countries. In addition, because the FDC was not available in China, the regimen had to be given in separate pills.

Table 3 and the accompanying graph present the prices of part of ARVs in China in 2011 following patent expiration of certain drugs, and negotiations with drugs companies.

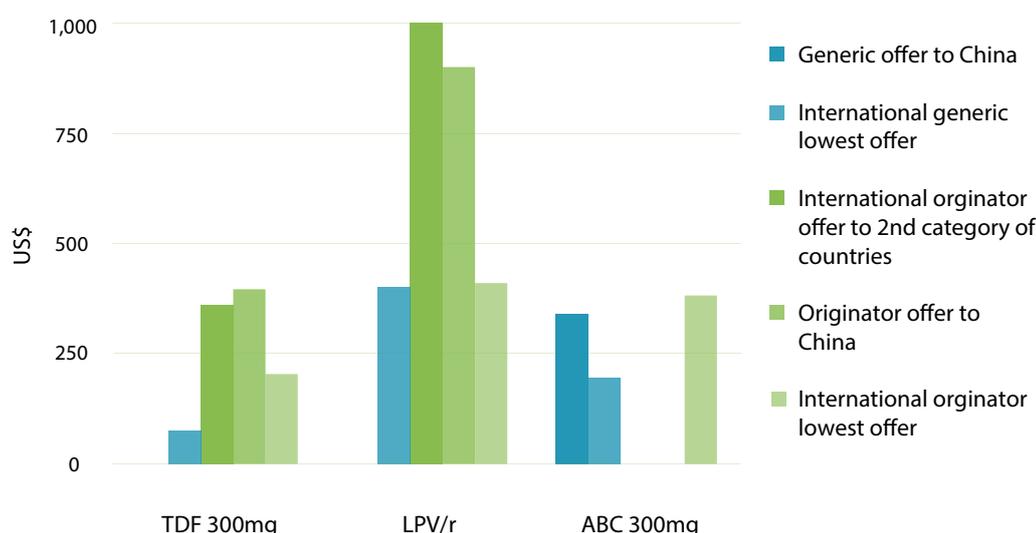
Comparing with 2006, although reduction of prices of certain drugs, such as LPV/r, is notable, patent protection and insufficient generic competition still keep prices of the three ARVs listed below much higher than the best international generic prices. Especially, when China is not

categorized by multinational pharmaceutical companies as eligible for differential pricing scheme, it is also not benefit from the lower prices from the originator.

Table 3: Prices Comparison of Selected of ARVs in China (2011)

(Unit of price: US\$, per patient/year)

	International originator lowest offer	Originator offer to China	Originator offer (second category of price)	International lowest generic offer	Chinese lowest generic offer
ABC 300 mg	382 ³⁶		N/A	195 ³⁷	341.11 ³⁸
Lopinavir/ritonavir (heat-stable tablet)	410 ³⁹	900 ⁴⁰	1000 ⁴¹	402 ⁴²	N/A (patent)
TDF 300 mg	204	396	360	76	N/A (patent)



Notes:

1. ABC's basic patent has expired in China. Though access to generic ABC is available, insufficient competition still keeps the prices of ABC in China higher than the lowest available generic prices.
2. LPV/r is patented in China on both compound and heat-stable formulation. Though efforts made in negotiation with the originator companies, the patent monopoly still blocks China from being able to benefit from the lower price from international generics. In addition, because the lowest originator prices only apply to low income countries, China is not eligible to get the price benefit as such.
3. TDF is patented in China, with ongoing invalidation proceedings to be closed. Though negotiation has dragged the price reduction, the originator price in China is still significantly higher than the international best prices for developing countries.

36 Ref. The 14th Edition of 'Untangling the Web of Price Reduction', MSF(2011), http://d2pd3b5abq75bb.cloudfront.net/2012/11/27/10/34/06/884/MSF_Access_UTW_15th_Edition_2012_updatedOct2012.pdf, last visited on December 06, 2012

37 Ibid.

38 Ref. WHO Global Price Reporting Mechanism (GPRM) database: <http://apps.who.int/hiv/amds/price/hdd/Default.aspx>, last visited on December 07, 2012

39 Ibid. Note 36.

40 Ref. Global Fund 'Price and Quality Report' (PQR)-'Transaction Summary' database, <http://apps.who.int/hiv/amds/price/hdd/Default.aspx>, for China price data, last visited on December 07, 2012

41 Ibid. Note 36.

42 Ibid. Note 36.

4. In order to accommodate different data sources in this table, the price information was chosen for 2011. However, it is important to note that in 2012, prices have had further changes. For instance, for TDF, the lowest international originator price now is US\$207 pp/y, and the lowest international generic price had been reduced to US\$57 pp/y.⁴³

Table 4 highlights the patent status of key ARVs in China as of 2010.⁴⁴ Given the wide range of patents granted in this field, patents may constitute a major obstacle to domestic production and import of generics and a source of high prices for ARVs in the country.

Table 4: Summary of HIV Drug Patents in China (2010)⁴⁵

Drug	Applicant	Subject Matter of Patent	Status
Abacavir	Wellcome Foundation Ltd	Abacavir (including succinate salt)	Patented
	Wellcome Foundation Ltd	New intermediates of abacavir	Patented
	Glaxo Group Ltd	Hemisulfate salt of abacavir	Patented
	Glaxo Group Ltd	Various salts of abacavir	Patented
	Glaxo Group Ltd	New formulation for pediatric use	Rejected
	Glaxo Group Ltd	New formulation for pediatric use	Pending
Atazanavir	Novartis AG	Atazanavir	Patented
	Novartis AG	Derivative compounds of atazanavir	Patented
	Bristol Myers Squibb Co	Bisulfate salt of atazanavir	Patented
	Bristol Myers Squibb Co	Process for preparing atazanavir	Pending
	Bristol Myers Squibb Co	Method of using atazanavir to reduce elevated LDL and/or triglyceride levels in HIV patients	Patented
Darunavir	G D Searle & Co	Intermediate compounds	Patented
	Tibotec NV	N-oxides, stereoisomers and racemic forms of darunavir	Patented
	Tibotec Pharm Ltd	Combination of darunavir with a cytochrome P450 inhibitor	Patented
	Tibotec Pharm Ltd	Pseudopolymorphic forms of darunavir	Patented
	Tibotec Pharm Ltd	Methods for preparing intermediate compounds of darunavir	Patented
	Tibotec Pharm Ltd	Process for preparing polymorphic and pseudopolymorphic forms of darunavir	Patented
Didanosine	Bristol Myers Squibb Co	Method for making didanosine	Pending
	Bristol Myers Squibb Co	New dosage form of didanosine	Patented
	Bristol Myers Squibb Co	Enteric coated composition of didanosine	Patented
Efavirenz	Merck & Co. Inc	Efavirenz	Patented
	Merck & Co. Inc	Efavirenz in combination with zidovudine, didanosine or stavudine	Patented
	Merck & Co. Inc	Crystallised forms of efavirenz	Patented
	Merck & Co. Inc	Process for obtaining crystallised forms of efavirenz	Patented
	Bristol Myers Squibb Co	Solid dosage forms of efavirenz	Patented

43 See. The 15th edition of 'Untangling the Web for Prices Reduction', MSF (2012), available at http://d2pd3b5abq75bb.cloudfront.net/2012/11/27/10/34/06/884/MSF_Access_UTW_15th_Edition_2012_updatedOct2012.pdf, last visited on December 06, 2012

44 At the time of completion of this report, some patent status listed in I-MAK report has changed. For instance, basic product patent on both Abacavir and Lamivudine have expired.

45 See. I-MAK China ARV patents report (2010) at <http://www.i-mak.org/patent-landscapes/>, last visited on December 05, 2012

Drug	Applicant	Subject Matter of Patent	Status
Elvitegravir	Japan Tobacco Inc	Elvitegravir	Patented
	Japan Tobacco Inc	Crystal forms of elvitegravir	Pending
	Gilead Sciences Inc	Use of elvitegravir with ritonavir and/or other ARVs for improving pharmacokinetics	Pending
Emtricitabine	Emory University	Methods for obtaining the racemic form of emtricitabine	Patented
Enfuvirtide	Trimeris Inc	Combination of enfuvirtide with didanosine, lamivudine or zidovudine	Rejected
	Trimeris Inc	Methods for synthesising enfuvirtide	Patented
Etravirine	Janssen Pharmaceutical N.V.	Etravirine	Patented
	Tibotec Pharmaceuticals Ltd	New analogs of etravirine	Pending
Fosamprenavir/ Amprenavir	Vertex Pharmaceuticals Incorporated	Amprenavir	Patented
	Glaxo Group Ltd	Liquid formulation of amprenavir	Rejected
	Vertex Pharmaceuticals Incorporated	Composition comprising amprenavir with lamivudine and/or zidovudine	Abandoned
	Vertex Pharmaceuticals Incorporated	Fosamprenavir	Pending
	Vertex Pharmaceuticals Incorporated	Isomeric forms of fosamprenavir	Patented
	Glaxo Group Ltd	Form I crystalline of calcium salt of fosamprenavir	Patented
Indinavir	Merck & Co. Inc	Combination of indinavir sulfate with zidovudine or didanosine	Lapsed
Lamivudine	IAF Biochem International, Inc	Enantiomer of lamivudine	Patented
	Shily Biolog Chemistry Co Ltd	Method for preparing enantiomer of lamivudine	Patented
	Glaxo Group Ltd	Liquid pharmaceutical composition comprising lamivudine	Patented
Maraviroc	Pfizer Ltd	Maraviroc	Rejected
		Salts, solvates and hydrates of maraviroc	Patented
		Polymorph of maraviroc	Pending
Nevirapine	Boehringer Ingelheim Chemicals	Process for making nevirapine	Patented
		Nevirapine hemihydrate	Patented
Raltegravir	Angeletti P. Ist Recherche Bio	Raltegravir	Pending
	Merck & Co. Inc	Potassium salt of raltegravir	Pending
Rilpiverine	Janssen Pharmaceutical N.V.	Rilpiverine	Patented
Ritonavir, Lopinavir and Ritonavir/ Lopinavir	Abbott Laboratories	Lopinavir	Patented
		Crystalline form of lopinavir	Patented
		Polymorph of ritonavir	Pending
		Amorphous form of ritonavir	Pending
		Soft gel capsule formulation of ritonavir, and ritonavir and lopinavir	Patented
		Soft gel capsule formulation of ritonavir	Patented
		Intermediate compounds for lopinavir	Patented
		Solid galenic formulation	Pending
		Solid pharmaceutical dosage forms of ritonavir, and ritonavir and lopinavir	Pending
		Prodrug of ritonavir and lopinavir	Pending

Drug	Applicant	Subject Matter of Patent	Status
Saquinavir	F.Hoffmann-la Roche AG	Saquinavir	Patented
		Method for preparing saquinavir	Patented
		New dosage form of saquinavir	Patented
		Process for making liquid capsules of saquinavir	Patented
Stavudine	Bristol Myers Squibb Co	Sustain release beadlets containing stavudine	Lapsed
Tenofovir Disoproxil Fumarate	Gilead Sciences Inc	Tenofovir disoproxil	Patented
		Tenofovir disoproxil fumarate	Patented
		Lithium alkoxide and tenofovir for preparing intermediate compounds of tenofovir disoproxil fumarate	Patented
		Formulations of tenofovir disoproxil fumarate for tropical application	Pending
		Prodrugs of tenofovir and their screening methods	Patented
Tpranavir	The Upjohn Co	Tipranavir	Patented
	Boehringer Ingelheim Chemicals	Oral dosage form of tipranavir	Patented
	Pharmacia & Upjohn Co	Method for improving pharmacokinetics of tipranavir	Patented
	Pharmacia & Upjohn Co	Pharmaceutical composition comprising tipranavir	Patented
Fixed Dose Combinations	Glaxo Group Ltd	Zidovudine and lamivudine	Patented
	Wellcome Foundation Ltd	Abacavir, zidovudine, lamivudine and emtricitabine	Patented
	Glaxo Group Ltd	Abacavir, zidovudine and lamivudine	Patented
	Glaxo Group Ltd	Amprenavir, zidovudine and abacavir	Withdrawn
	Glaxo Group Ltd	Abacavir and lamivudine	Withdrawn
	Tibotec Pharm Ltd	Rilpiverine, emtricitabine, lamivudine, zidovudine, abacavir and/or tenofovir disoproxil fumarate	Pending
	Merck & Co Inc	Indinavir, lamivudine and zidovudine	Patented
	Glaxo Group Ltd	Amprenavir, zidovudine, emtricitabine and lamivudine	Withdrawn
	Bristol Myers Squibb and Gilead Sciences Inc	Efavirenz, emtricitabine and tenofovir disoproxil fumarate	Pending
	Tibotec Pharm Ltd	Darunavir, tenofovir disoproxil fumarate and lopinavir	Pending

Notes:

1. Only patents held by originator companies were included in the landscape. The searches also revealed patents related to processes and fixed dose combinations held by Chinese and Indian companies.
2. The landscape reveals that for the majority of ARVs, patents covering the base compound (active ingredient) have been granted. However, patents covering the base compounds for nevirapine and ritonavir do not appear to have been filed in China. Due to the translations of claims not being available, it is also unclear whether the base compounds of indinavir and lamivudine have been patented.
3. In addition to patents claiming the active ingredients, patents for polymorphs, key formulations and processes for ARVs have been applied for or granted in relation to a number of ARVs.

Source: Initiative for Medicines Access and Knowledge

The WHO-recommended second-line treatment (ABC+ddl+LPV/r) was not available in China and MSF in 2006 paid about US\$13,000 per patient per year when importing from Hong Kong. This made it nine times more expensive than the international originator's lowest offer of US\$1,424. This is because all second-line drugs (except indinavir) were patented in China, preventing their generic production, and some originators were simply delaying marketing their drugs in China. The situation only got worse when more patients started to need second-line drugs, as a second-line regimen costed 55 times more than a first-line in China.

Additionally, companies that produce formulations have not made them available at affordable prices in China either. In 2006 the cheapest treatment for children was eight times more expensive than the cheapest treatment for adults in the absence of FDCs. The MSF study concluded that intellectual property protection, among other factors, has had a wide-ranging impact on public health and access to medicines in China including: restrictions on drug choice, lack of availability of needed drugs, and high prices for originator drugs.

B.2.2 The case of lamivudine (commonly known as 3TC)⁴⁶

(a) Availability of 3TC in China

For a long time, a big gap in the national treatment programme was the sustainable supply of 3TC that is central to ART, as recommended by the WHO. Since 3TC is also used in a different dosage for treatment of chronic hepatitis B and there is no national free treatment available, the cost burden rests almost entirely on the patients (CYN 234 or about US\$29 per box at 2006 prices).

The 2007 situation, when GlaxoSmithKline's (GSK) monopoly triggered concern among public health groups, was as follows:

- Only 3TC 100 mg (for hepatitis B, sold under the brand name Hoptodin) was marketed and this was the fifth biggest product for GSK in China, worth US\$41 million of profit a year.
- 3TC 150 & 3TC 300 mg (under the brand name Epivir) were registered in China but effectively not marketed.
- The only combination containing 3TC that was available was ZDV+3TC (under the brand name Combivir) that is supplied by GSK.
- Combivir cost US\$2,649 per person per year. The best price available was US\$197 per person per year for Cipla's generic that is a WHO prequalified drug (Combivir was 13 times more expensive than this generic product).

3TC has been included in the WHO Model list of essential medicines since 2006. The WHO guidelines for antiretroviral therapy for HIV recommended this drug to be used for first and second line treatment for adults and adolescents, and for first line only for children. The strength of 3TC in HIV treatment is that, it is powerful to suppress many different types of HIV virus strains, and those virus strains that become resistant to 3TC are often vulnerable and much easier to be suppressed by other ARVs. Therefore, 3TC is essential in both first line and second line HIV treatment, and is one of the optimal and most widely used ARVs in the world.

When the Chinese government launched a national AIDS treatment programme in 2003, there was no appropriate formulation of 3TC for treatment. In the retail market, only the formulation with dosage for treating hepatitis B was available from GSK. No generic 3TC was available due to various exclusive rights enjoyed by GSK since the 1990s even though China did not provide for product patents yet at that time (see below on those other exclusive rights).

As a consequence, the national programme did not include 3TC when it first began providing ART because of both the prohibitive price and lack of domestic production. Doctors have attributed

⁴⁶ The information on the case study of lamivudine was provided by MSF. See especially: "Briefing Note - Accessibility of Lamivudine (3TC) in China" (August 2006, updated March 2008). Reference was also made to Hu Yuanqiong, Wang Xiangyu, *et.al.* (2009) 'Multi-sector Approaches on Improving Access to ARVs in China', in ABIA (ed.) *Intellectual Property Rights and Access to ARV Medicines: Civil Society Resistance in the Global South*, Brazilian Interdisciplinary AIDS Association and Ford Foundation, Rio, P82-110; online version available at: http://www.abiaids.org.br/_img/media/Intellectual_Property_internet.pdf, last visited on December 05, 2012

high levels of side effects and negative impacts on patient adherence, to the absence of the medicine. Another locally available ARV, didanosine, was used instead of 3TC, giving rise to major side effects when prescribed in association with another first-line ARV (stavudine).

From late 2004 for the next few years GSK donated 3TC on a negotiated basis with the MOH, the terms of which were confidential. There were accounts of 3TC shortages at treatment sites from time to time raising questions of predictability and sustainability of supply if donations are relied upon.

(b) Access Barriers to 3TC in China

The domestic pharmaceutical industry in China is a major supplier of the 3TC active pharmaceutical ingredients in the world, but the finished product had been only available in China from GSK. GSK had maintained its market monopoly on 3TC since the 1990s.

An agreement was signed between the MOH and GSK on 3TC 300 mg in July 2006/2007 providing for a donation of 118,000 boxes for 20,000 persons. If a similar quantity of generic 3TC had been purchased it would have cost less than US\$1million (US\$8.4/box). The terms of the agreement were confidential.

Process patents: The original patent application on 3TC was filed in 1990 in China, at a time when China did not grant patents on pharmaceutical products, but only on processes. Product patents were allowed only in 1993 when the Patent Law of China was revised to implement the country's obligations under a bilateral agreement with the United States.

GSK also owned a group of process patents covering the manufacturing process of 3TC, and according to analysis by Médecins Sans Frontières, which provided a strong and broad protection that could also affect 3TC as a product. In May 2007, GSK published a statement on its China website, announcing that they owned five process patents that still were valid in China.⁴⁷ GSK further claimed that "the protection provided by Patent no. 99126580.7 extends to *all* finished products of lamivudine that are suitable for pharmaceutical use *and* any unlicensed manufacture, sale or use of a finished pharmaceutical product of lamivudine will infringe this patent"⁴⁸.

However, according to Médecins Sans Frontières, the patent application ZL99126580.7 was a divisional application of No. ZL94109429.4, which itself was a divisional application of Patent No. ZL91102778.5, whose filing date is 30 April 1991, with a priority date of 2 May 1990. Since divisional applications cannot go beyond the scope of disclosure contained in the initial application (according to Article 43 of the rules of implementation of the Patent Law), this patent could only be a process patent - as products patents were not available at that time in China. It was therefore surprising that GSK made allegations that such a patent could block *all* finished products.⁴⁹

Regulatory protection: In the absence of product patents before 1993, there were two types of protection on 3TC accorded under China's drug administration regulations by the SFDA. The effect was similar to a patent protection, which also blocked the introduction of generic versions of the drug.

Administrative Protection: This was a type of retrospective market exclusivity awarded in China to medicines that were patented abroad, but not in China, between 1 January 1986 and 1 January 1993. The *Regulations on Administrative Protection for Pharmaceuticals* were approved by the State Council on 12 December 1992, and entered into force on 1 January 1993. In essence, administrative

47 <http://www.gsk-china.com/english/html/newscentre/china-news.asp> - "Statement on Lamivudine patent position" dated 15 May 2007.

48 Emphasis added.

49 A patent search was conducted by Medecins Sans Frontieres and an analysis made by their in-house legal experts.

protection was created to fill the void of product patents, which were not available in the country before 1993. Although this protection was the result of the bilateral agreement with the US in 1992, it was eventually extended to drugs patented in any other country.

Article 1 stated that the Regulations were “enacted with a view to expanding economic and technological cooperation and exchange with foreign countries, providing Administrative Protection to the lawful rights and interests of the owners of the exclusive right of foreign pharmaceuticals”.

Article 3 provided that “Enterprises and other organizations and individuals from the country or the region, which has concluded bilateral treaty or agreement with the People’s Republic of China on administrative protection for pharmaceuticals, may apply for Administrative Protection for Pharmaceuticals in accordance with these Regulations”.

Article 13 provided for that a Certificate for Administrative Protection for Pharmaceuticals would last for seven and a half years from the date of issuance of the Certificate.

Even in the absence of product patents, the Administrative Protection accorded to 3TC from April 1999 to October 2006 succeeded in preventing the domestic production and importation of generic 3TC, and thus also FDCs and paediatric formulations comprising 3TC.

New Drug Protection (NDP): This type of protection was established in 1999 in order to encourage technology transfer. Applicants for the registration of new drugs could be granted market exclusivity on the condition that they produced the new drug in China, or transferred the technology to a Chinese manufacturer within two years of the NDP certificate being granted.

Article 18 of the Administrative Protection of Drugs, National Drug Administration Bureau (19 December 1992) stated: “... the State Council’s Department of Health and its divisions in all provinces, autonomous regions and cities shall not allow the manufacturing or sales of such drug by another party or entity.” However, there was a safeguard clause that allowed SFDA to “license others for production” in the public interest.

In exchange, SFDA would prohibit other companies from manufacturing the drug, and could not accept applications for registration of generic versions of the drug until the protection period has expired. In the latter case, this extended *de facto* the market exclusivity by an additional one to three years, the average time needed by SFDA to register a drug.

NDP was granted until 2002, when it was abolished and replaced with another system of exclusivity called the ‘drug monitoring period’. Nevertheless, all drugs for which NDP was obtained prior to 15 September 2002 maintained their full term of protection for six, eight or twelve years, depending on the category to which the drug belonged.

3TC obtained an NDP that was valid until December 2006. During the period of protection, SFDA was prohibited from even accepting applications for registration of generic versions of the drug.

Data protection: In China, applicants who register a drug containing a ‘new chemical entities’ can obtain a market exclusivity based on the protection of test data. Generic companies cannot rely on *undisclosed* clinical trial data, submitted by the original manufacturer, in order to register a generic version of the same drug for six years from the date of registration in the country⁵⁰ (Article 35 of the *Regulations for Implementation of the Drug Administration Law*, 2002, revised 2007).

⁵⁰ Originating in the US, it is known as ‘data exclusivity’ in the US and other jurisdictions that apply a similar regime.

China committed itself to provide such data protection, as a part of the obligations assumed as a result of its accession to the World Trade Organization in 2001.⁵¹ The accession negotiations were completed before the 2001 Doha Declaration on the TRIPS Agreement and Public Health (hereinafter 'the Doha Declaration')⁵², which confirmed the right of WTO Members to implement intellectual property rights in a manner that promotes public health (see section D.1 below).

The TRIPS Agreement does not require 'data exclusivity' – its provisions on data protection require less burdensome measures to be implemented by WTO members (see section E.4 below). China's regulations provide for an obligation and scope of protection that exceeds the requirements of the TRIPS Agreement. There is therefore a clear argument for China to amend its data protection provisions in light of the Doha Declaration, to foster access to essential medicines for its population. In addition, there are a number of safeguards that could be adopted in China, in the spirit of the Doha Declaration on the TRIPS Agreement and Public Health, to minimize the negative impact of such provisions and to safeguard public health.⁵³

“Chill factor” on domestic generic manufacturers: In anticipation of the expiry of the Administrative Protection (October 2006) and New Drug Protection (December 2006) over 3TC, several Chinese manufacturers submitted applications to register generic 3TC. However, beyond the preliminary stage there were no further actions to fulfill registration requirements. It is understood that domestic manufacturers were hesitant because of concerns over possible infringement of GSK's process patent.⁵⁴ The May 2007 announcement by GSK of its broad process patent and the precedent set by the courts' confirmation of the validity of patent claims over Viagra (active ingredient sildenafil citrate) also contributed to creating a 'chill factor'.

Viagra entered the Chinese market in July 2000. It was granted a patent in September 2001 that would last until 2014. In October 2001, 12 domestic companies opposed the patent because drugs produced by some Chinese companies had already been using the active ingredient of Viagra in local drugs. In July 2004, following a re-examination the State Intellectual Property Office (SIPO) declared the patent for Viagra invalid in China because it did not conform with Article 26 of the Patent Law which states that a patent application must include a description of the drug "in a manner sufficiently clear and complete so as to enable a person skilled in the relevant field of technology to carry it out". In September 2004, Pfizer filed an appeal against the ruling. The case went to court in April of 2005. In June 2006, a Beijing court ruled in favour of Pfizer. GSK's assertion (in August 2006 and the web posting of their statement on 15 May 2007) of the broad process patent claim and threat of infringement actions against generic manufacturers and importers is understood to have created a chill factor too.

However, an important development also took place later with regard to ARVs. A domestic manufacturer, Anhui Biochem United Pharmaceutical Co., Ltd successfully challenged a GSK patent and won the case through an official adjudication by a SIPO patent re-examination committee on 30 December 2010. Anhui Biochem had succeeded in obtaining registration for the marketing of its generic product (a combination of zidovudine + 3TC) shortly before the patent re-examination decision. It is the only company that is marketing this generic FDC at the time of writing. The only other FDC currently in the market is GSK's Combivir. For the generic version of single dose 3TC, there are five domestic manufacturers and one joint venture with GSK, which obtained the registration for various dosages in 2010, 2011 and 2012 respectively.

51 World Trade Organization, Report of the Working Party on the Accession of China. WT/MIN(01)/3. Paragraph 284. 10 November 2001. Available at: www.wto.org

52 See WT/MIN(01)/DEC/2.

53 Carlos Correa. "Proteccion de Productos Farmaceuticos y Agroquimicos ('Productos Regulados') en DR-CAFTA. [Protection of Pharmaceutical Products and Agrochemicals ('Regulated Products') in the Dominican Republic-Central American Free Trade Agreement]." Working Paper. April 2006.

54 Communications between TWN and government officials and industry observers in March and April 2008.

B.2.3 Stock-outs and shortages

In response to the concerns and growing public criticism by the HIV community regarding the lack of supply of ARVs, GSK donated consignments of 3TC to the MOH for its national treatment programme for several years.

Over the second half of 2007, while treatment was dependent on an ongoing GSK supply agreement, numerous persons living with HIV reported that there was a shortage of 3TC supplies in different treatment sites in China, including Shanghai, Jiangxi, and Henan provinces, causing considerable alarm among the HIV community, UN agencies and international NGOs involved in treatment and care. The Central Government had to dispatch a few thousand dosages to Henan province, one of the affected areas.

Assurance came from a representative of the MOH that while there was some concern in some places, there was no risk of 3TC shortages as a whole. Most patients live in remote rural, often poor, areas and there is a long supply chain from the central to the provincial, county and finally village level. It is still a challenge for provincial governments to plan for purchase of 3TC a year in advance due to the geographical complexity of China and the different degree of capacity at every level of the supply chain.⁵⁵

While planned procurement and supply chain management are important factors to ensure that there is no interruption in ARV treatment, there are concerns among many in the care and treatment community that dependency on a limited number of originator companies and donations is not sustainable. This is particularly so in the light of the government's policy to provide selected free ARVs.

Médecins Sans Frontières, which has had field experiences since 2003 in two provincial treatment centres, reported that they had been contacted numerous times regarding stock-outs of ARVs; the healthcare facility concerned has either run out of the drug, never stocked the drug or have insufficient quantities to meet patients' needs. This means that patients must often turn to the private market. In the absence of publicly available national data on stock ruptures, anecdotal evidence suggests that 3TC and efavirenz (EFV) are often not available. Both of these are included in the free national ART list and form part of the first-line regimen.⁵⁶

According to MSF, the costs of treatment and care were significant, even when there was access to free ARV drugs.⁵⁷ However, the cost per patient had decreased as a result of the availability of cheaper drugs and the access campaign. The global campaign for access to affordable drugs has contributed to the lowering of international prices that is also enjoyed by a number of countries.

In 2005 the government price for a generic ARV combination (stavudine or zidovudine, didanosine, and nevirapine) was about CNY 3,500 (US\$437 at 2005 prices) per person per year. There was no publicly available information regarding the government price paid for a 3TC-based combination, although this was the recommended first-line regimen, as the terms of supply from GSK for 3TC were kept confidential.⁵⁸

In addition to the expenses that patients already faced, increased costs resulting from the need for access to more expensive second-line AIDS therapy grows – it is estimated that prices can

55 Briefing by Dr. Han Meng Jie (Director, State Council AIDS Working Committee Office) at the meeting of the UN Theme Group on HIV/AIDS Care and Treatment, 27 March 2008.

56 At 2006 prices, one month's supply of 3TC (150 mg, 60 tablets) costed CNY 1300 (US\$162), and a month's supply of EFV (600 mg, 30 tablets) CNY 619 (US\$77) in the private market. MSF, *The Cost of AIDS Care in China – Are Free Antiretroviral Drugs Enough?* (2006), at page 9.

57 Ibid.

58 Ibid.

range from 7 to 28 times as much as first-line regimens.⁵⁹ With the health care reform and policy to expand the government's provision of ART, the cost of ARVs assumes even greater importance.

Unless long term sustainability through domestic production is in place, the 3TC experience may be repeated such as in the case of tenofovir, a first line ARV in the treatment regime of China, crucial for the treatment of HIV as well as of chronic hepatitis B.

B.2.4 Continuing challenges to improve access to ARVs

According to the Joint Assessment of HIV/AIDS Prevention, Treatment and Care in China (2007), prepared by the State Council AIDS Working Committee Office and the UN Theme Group on AIDS in China, implementation of the 'Four Free, One Care' initiatives had been uneven, with poor linkages between different services. One challenge is the difficulty in obtaining supplies of second-line ART drugs.⁶⁰

Among the recommendations of the Joint Assessment were:

- Increase support to local governments to strengthen treatment policies and increase investment to implement the 'Four Free, One Care' policy.
- Review the procedures for AIDS treatment in order to increase the adherence of treatment. Continue to facilitate second-line drug research and development and their registration.

As the number of paediatric cases has increased, some paediatric drugs have been included in the plan for domestic production but it is not clear what the government has in mind.⁶¹

Meanwhile, the reality is that China's current ARV choices are very limited even though the country is a global supplier of active pharmaceutical ingredients for ARVs. Patent restrictions are a major obstacle to more domestic production of end products. Even the import of cheaper originator or generic ARVs available in the international market is currently prevented or subject to conditions imposed by the originator company (or its licensee).

Where the ARVs are available, the cost of patented ARVs is high and so increased need will also strain the public health budget and put the ARVs out of the range of almost all those who need treatment.

A big gap in the national ARV treatment programme remains if there is no sustainable and affordable supply of lamivudine (3TC). Generic Fixed Dose Combinations (FDCs) with 3TC were also not available in China until 2011 when the last GSK patent expired (and even then there is only one domestic company producing generic zidovudine+3TC at the moment). Paediatric formulations are not economically attractive as the number of treatment recipients under the government scheme is small, so there is no motivation to consider generic production – in that scenario patents pose additional barriers. Such situations show the problems of patients in terms of adherence and drug resistance.

In meeting the problems of HIV/TB co-infections, appropriate FDCs for TB treatment are also needed, but not available. Given the high burden of pills and its impact on treatment compliance, FDCs are again very urgently needed.

59 Ibid.

60 See footnote 2 at page 35.

61 Ibid. at page 26.

Second-line ARVs are now the next big gap for both AIDS and TB treatment. While this is still limited for PLHIVs, there is no government scheme for second-line treatment for those with TB.

Table 5 reveals the patent landscape of the FDC of ARVs containing TDF in China. It indicates that in the future scaling up and upgrading ART treatment in China, using second-line ARVs and especially FDCs would face great challenge with accessibility and affordability due to patent protection.

Table 5: Patent Status of FDC ARVs containing TDF in China⁶²

	name	Originator/Inventor	International Marketing Time	Patent Status in China	Available in China
TDF/FTC	Truvada	Gilead	2004	patented	N/A
TDF/FTC/EFV	Atripla	Gilead/Merck/GSK	2006	Patented	N/A
TDF/3TC/EFV	Cipla &Matrix			Patented	N/A

Since these are mostly new drugs, the patent duration remains longer unless steps are taken to maximize the flexibilities that China is entitled to under the World Trade Organization's Agreement on Trade-related Aspects of Intellectual Property Rights. This is discussed in Section E.

Unaffordable 3TC products also threaten people living with chronic hepatitis B, whose plight is worse because there is currently no government coverage for their needed medicines.

C CAN CHINA MEET ITS OWN ARV NEEDS THROUGH DOMESTIC PRODUCTION?

The Chinese government has a policy to promote the development of the domestic pharmaceutical industry as well as provide a supportive business environment for foreign pharmaceutical companies.

Since 2002 the State Council has approved customs and VAT exemption for the import of selected ARVs for a period of five years for each approval.

In 2003 approval was given for the VAT exemption of production and circulation of selected ARVs produced by domestic designated companies (for the period 1 July 2003 to 31 December 2006).

On 5 January 2007 customs and VAT of import were exempt for the import of ARVs. The amount of tax-free import of ARVs in total was US\$132 million, with the annual limits specified.

On 17 April 2007 another State Council approval for the VAT of production and circulation to continue to be exempt for selected ARVs produced by designated domestic companies for the period 1 January 2007 to 31 December 2010.

62 See. Hu Yuanqiong (2009); 'Pharmaceutical Patent and Access to Medicines: Continued Challenge to Health Justice in China', (44) *China Development Brief*, P24-26, available at: <http://www.chinadevelopmentbrief.org.cn/qikanarticleview.php?id=1052>, last visited on December 04, 2012

Similar exemptions have been made for the period 2011 to 2014.

This was the result of the coordination and joint efforts by the State Council AIDS Working Committee Office, the Ministry of Finance, the State Administration of Taxation, the National Development and Reform Commission and the General Administration of Customs. The exemptions help to stabilize the price of ARV drugs and the price of some drugs decreased. As the number of paediatric cases increased, some paediatric drugs have been included in the plan for domestic production.⁶³ However there are no available details on the plan for paediatric drugs.

C.1 An overview of China's pharmaceutical industry

The development of the Chinese pharmaceutical industry is mainly driven by disease treatment, health recovery and the birth rate of a population of more than 1.3 billion. The investment in healthcare is growing rapidly in China in recent years. This has resulted in the fast growth of China's pharmaceutical industry. It is also one of the fastest growing pharmaceutical markets with 15-20 percent average annual growth since 1998.

China's pharmaceutical industry has an educated workforce, entrepreneurial culture, relative low labour and resource costs although these have been rising in recent years. All these factors contribute to the fast growth of China's pharmaceutical industry. Now China has emerged as a strong player of API and finished pharmaceutical products manufacturing.

The Chinese industry is dominated by generic production with an estimated 97 percent of drugs produced by domestic suppliers.

In 2009, the gross production of China's pharmaceutical industry was about US\$137 billion, which was increased by 21 percent.⁶⁴ In recent years, there are almost 5,000 companies with SFDA Good Manufacturing Practice (GMP) certification. More than 160 products of nearly 80 companies have passed European GMP certification. 317 API or intermediates have acquired DMF registration numbers of the US FDA.⁶⁵

China is the largest supplier of API in the world. API constitutes a major trading component in the export and import of China pharmaceutical products, which accounts for 60.55 percent. From January to August 2011, the export of API from China was 4.02 million tons, an increase of 32.87 percent compared to the previous year. The value of exports also increased by 28.81 percent to US\$14.83 billion. However the average price of the exported products fell by 3.05 percent.

China is still at the lower end of the supply chain in global pharmaceutical production. The major markets of China's API are India and other Asian countries, which account for 45.51 percent of the API exports. Following the Asian market are Europe and North America. India accounts for 14.45 percent of the value of API exports and US is the second one with 13.44 percent. The top 10 countries for China's API export are India, US, Japan, Korea, the Netherlands, Brazil, Italy, Spain and Belgium.⁶⁶

Currently China's pharmaceutical industry can provide more than 1,400 APIs and over 4,000 finished pharmaceutical products. Its API industry is represented in almost all segments, such as anti-infectives, cardiovasculars, gastrointestinal and metabolism drugs and anti-inflammatory

63 See footnote 18.

64 http://www.stats.gov.cn/was40/gjtj_detail.jsp?searchword=%D6%C6%D2%A9&channelid=6697&record=17

65 <http://wenku.baidu.com/view/0dfade11cc7931b765ce1586.html>

66 <http://www.cccmhpie.org.cn/Pub/1757/39637.shtml>, published on October 14, 2011.

drugs. In the production of vitamins, antipyretic and analgesic, hormone, penicillin and β -lactam, Chinese manufacturers have comparative advantages.⁶⁷

At present, there are dozens of manufacturers that have obtained registration for their ARV drugs in China. More than 10 manufacturers are in actual operation for ARV production.⁶⁸ Among them, Northeast Pharmaceutical Group Co., Ltd. is the earliest and biggest manufacturer with the most ARV products in China, which has capacity to provide nine dosage forms of four drugs in HIV cocktail therapy.⁶⁹ Other major ARV manufacturers are Desano Pharma, Matrix Pharma Group (Xiamen) Ltd., Zhejiang Huahai Pharmaceuticals Co., Ltd., and Anhui Biochem United Pharmaceutical Co., Ltd.⁷⁰ Anhui Biochem is the only manufacturer of a generic fixed dose combination of 3TC + zidovudine. Some Chinese manufacturers have the capacity to produce the API of TDF, e.g. Desano Pharma and Anhui Biochem.⁷¹ But in China, the only registered TDF product is TDF tablets, 300mg, with the brand name VIREAD as an imported drug. It is registered by Gilead and manufactured by Pharmicare Limited trading as Aspen Pharmicare.⁷²

A recent survey indicated that the low interest of the Chinese pharmaceutical companies to produce generic ARVs was due to low profit margins and regulatory barriers.⁷³ As a result, multinational corporations such as GSK, BMS and Roche, dominate the ARVs market in China. For example, finished product of Tenofovir Disoproxil Fumarate (TDF) has to be imported. GSK has signed an exclusive licensing agreement with the originator (Gilead) for launching the drug in the market at its own expense.⁷⁴

Although Chinese manufacturers can produce some cheaper ARVs, they largely concentrate on the production and export of API.⁷⁵ By 2008, China had become a major exporter of APIs of ARV. Some small or medium sized companies in Zhejiang and Jiangsu Provinces only produce the APIs or intermediates of ARV for international markets, such as Changzhou Huaren Chemical, Taizhou Healtech Chemical and Hangzhou Coben Chemical Industry. In 2010, 873 tons of ARVs were produced in China, with the potential of producing approximately 4.5 billion generic pills, but only 85 million (1.8 percent) of such pills were produced during that year in China⁷⁶.

The three biggest markets of API of ARV are South America, India and Thailand. Most of the Chinese ARV manufacturers have stepped in these markets. Now the value of exports to these ARV markets is over US\$100 million. For example, MCHEM, a Xiamen, Fujian Province based Chinese ARV manufacturer has been certified by the Brazilian government as one of three global ARV API suppliers. Meanwhile, MCHEM has also registered their finished ARV products in 13 African countries and acquired the permission for launching products in these countries.⁷⁷

All companies with products registered on the local market have to meet the current China GMP standards, and these have been revised akin to those in the European Union and implemented in

67 Comparison between China and India Pharmaceutical Industries <http://www.chinaburn.net/Article/ShowArticle.asp?ArticleID=138>

68 <http://news.fh21.com.cn/20060119/015100%281%29.shtml>

69 <http://stocks.caixun.com/content/20110817/NE02rpd.html>

70 http://www.zyzzhan.com/company_news/Detail/14235.html & <http://www.bcpharm.com/en/>

71 http://www.bcpharm.com/en/info.asp?base_id=23&second_id=23001 & http://www.desano.com/english/product/api_1.html

72 <http://www.sfda.gov.cn>

73 Lucy Chen, Mark Stirling, Zhao Chenyue and Bernhard Schwartländer (2102), China's capacity in producing quality ARVs for Domestic And Global Needs, study produced for UNDP.

74 http://www.zyzzhan.com/company_news/Detail/14235.html

75 http://news.800pharm.net/2011-03-03/23963_1.html

76 Lucy Chen, Mark Stirling, Zhao Chenyue and Bernhard Schwartländer (2102), China's capacity in producing quality ARVs for Domestic And Global Needs, study produced for UNDP.

77 'Advantages of China in ARV industry' <http://www.cfi.net.cn/newspage.aspx?id=20061030001462&AspxAutoDetectCookieSupport=1>

2011. Increasingly a number of companies are also seeking registration in industrialized country markets. In an effort to rationalize and streamline the industry and upgrade the safety and quality of domestic production, the SFDA – which is responsible for regulating research, registration, GMP quality, production and market circulation - has reviewed compliance by domestic producers of the new GMP standards adopted in 2011.

Desano's APIs (AZT, 3TC, NVP, d4T) have been qualified by the WHO Pre-qualification programme. Huahai's API and a formulation (NVP) production were inspected by the US Food and Drug Administration (FDA) and approved in 2007.

The WHO continues to work with the Chinese authorities and generic companies to put in place the processes and conditions for WHO pre-qualification status of APIs and finished products. So far, only the nevirapine tablet of Huahai Pharmaceutical Co. Ltd has acquired the pre-qualified status, which means no other finished ARV product made by Chinese generic companies can be purchased by the WHO or other global HIV programme.

C.2 Multinational corporations (MNCs) outsourcing to China

The general trend within the global pharmaceutical industry is API outsourcing. For example, AstraZeneca was one of the latest global players with plans to gradually withdraw from making its own active API and to use China as "the pinnacle of its new outsourcing plans"⁷⁸. In 2008 AstraZeneca was producing 85 per cent of its APIs at its own manufacturing sites and outsourcing the remainder; however, as part of its Asia strategy, the firm planned to phase out of this business over 5-10 years.

The company announced its intention to change its current "in China for China" strategy towards an "in China for global" strategy whereby China will eventually account for 90 per cent of all its global purchases. It set up a dedicated sourcing centre in Shanghai at the beginning of 2007, which sources APIs and chemical intermediates, along with other outsourcing products and services (e.g. packaging materials, contract R&D services, laboratory equipment and chemicals, contract formulation and packing) for AstraZeneca's global business.

The company, which spends US\$9 billion a year on purchasing, said it will use the China sourcing centre to make purchasing savings of 10 percent over the period 2008-2010. China's attractions, according to AstraZeneca, include the lower cost of goods, lower investment costs, shorter lead time and the access to the Asian talent pool as well as "improvements in intellectual property protection and the quality of manufacturing in China". Government and regulatory body attempts in the country to improve the business environment and conduct within the pharmaceutical industry were also cited.

In late 2006, Pfizer Centre Source decided to outsource the manufacture of some of its APIs to two Asian contract manufacturers, ScinoPharm of Taiwan and Shanghai Pharmaceutical of China, to "enable more cost-efficient API production". The two firms added manufacturing capacity to deal with the new contracts.⁷⁹ Pfizer said it would transfer the late-stage processing of 18 steroid API and intermediate products to the new manufacturing partners in three phases over the period 2007-2010, beginning first with the commodity APIs that involve the less sophisticated chemistry. The high cost of production in the US was cited as a factor for the shift. However, Pfizer also made it clear that they want "to keep the more technical and complex early-stage processes in-house".

⁷⁸ China to play starring role in AstraZeneca API outsourcing <http://www.in-pharmatechnologist.com/news/printNewsBis.asp?id=77963> (Downloaded 6 July 2007)

⁷⁹ Ibid.

A concern over the outsourcing by MNCs to Chinese companies is that the latter will become 'locked' into relationships that delay or even prevent domestic generic end products from being made for the domestic market and for other developing countries in need of affordable essential drugs. This concern is reinforced by the trend in India, where the implementation of pharmaceutical patents and moves by originator companies to take over or merge with Indian generic producers, may change the profile of the generic sector in the world's largest supplier of generic ARVs.

C.3 Prospects for China

From the above discussion it can be seen that China can potentially be a supplier of finished ARV products for the domestic market as well as for export to other countries, especially developing countries that have great need for affordable ARVs and other essential medicines.

As a leader in API production, China can also be a bigger supplier of API and related-technology to other developing countries to strengthen generic production in those countries. Generic medicines production can be an important component of Chinese overseas investment and development assistance programmes, such as the China-Africa cooperation initiatives.

China's foundation in science and technology can also contribute to the research and development of innovative pharmaceutical products (medicines, vaccines, medical devices, etc) for both the domestic and global markets.

In order to fulfill these potential prospects, China would need to formulate and implement a set of policies, including an appropriate intellectual property strategy that maximizes the use of the TRIPS Agreement flexibilities discussed below.

Importantly, on 13 January 2012 the State Council approved the *China Action Plan to Prevent and Control HIV/AIDS during the 12th Five-Year Plan⁸⁰ Period (2011-2015)*. Of particular significance for access to affordable medicines with regard to intellectual property and domestic production is the following:

"...Commerce, industry and information, intellectual property rights and health authorities shall explore the feasibility of obtaining licenses for production of imported, high cost, patented drugs by domestic enterprises to substantially reduce costs of drugs. Development and reform, food and drug supervision, industry and information and health departments shall strengthen guidance and coordination of domestic pharmaceutical enterprises to speed up research and development, production, examination and approval of HIV/AIDS medications."⁸¹

D MAXIMISING FLEXIBILITIES IN PATENT LAW FOR PUBLIC HEALTH

For a long time, patents on pharmaceutical products and chemical substances were the exception rather than the rule in many countries, including developed ones. Many countries would grant patents on the processes for making the products, but the products themselves could not be subject to exclusive rights.

⁸⁰ The 12th Five Year Plan is China's national development plan issued every five years.

⁸¹ China Action Plan to Prevent and Control HIV/AIDS during the 12th Five-Year Plan Period (2011-2015) (English version in draft, April 2012), p. 11.

By the late 1980s pharmaceutical corporations and other business allies succeeded in getting the trade and commerce departments of governments in the US, the European Union and Japan to push for the establishment of a new set of international rules on intellectual property in the context of GATT, which eventually materialized in the Agreement on Trade-Related Aspects of Intellectual Property Rights. This was one of the components of the final package of trade agreements of the Uruguay Round negotiations that also established the World Trade Organization.

The TRIPS Agreement put in place a comprehensive treaty on intellectual property that reduced the ability of countries to design their own appropriate national intellectual property system. It required all member governments to give product patents in all sectors with additional protection for process patents. A Pfizer corporate leader celebrated this triumph as an example of good industry-government partnership in an advertised editorial in *The Economist* weekly.⁸² He openly wrote about how the TRIPS Agreement was the result of industry lobby and that the initial draft of the treaty was formulated by industry.

Developed countries that are WTO Members ought to implement TRIPS obligations from 1 January 1995. This was not in general a major problem as the TRIPS standards and obligations were based on the legal systems existing in those countries. Developing and least-developed countries (LDCs) were given transition periods to implement most of the TRIPS Agreement obligations.

Developing countries had to implement the TRIPS Agreement by 1 January 2000. LDCs had a 10-year transition period so their implementation deadline was 1 January 2006. On 29 November 2005, LDCs as a group were granted an extension of the transitional period “until 1 July 2013 or until such a date on which they cease to be a least developed country Member whichever date is earlier” (WTO Doc. IP/C/40).

For pharmaceutical products LDCs have an even longer period, until 1 January 2016, before they need to provide for pharmaceutical patents and to protect undisclosed information on pharmaceutical products for purposes of market registration. LDCs have the right to seek further extension if needed.⁸³

Despite the transition periods for developing and LDCs, in reality many countries, because of unawareness, external pressures or inadequate technical assistance, implemented TRIPS obligations before they needed to do so. Many countries also enacted national patent laws that go beyond the TRIPS requirements.

The transition period played a crucial role in the case of India. India's Patents Act 1970 had been formulated with one important goal: to develop a strong domestic generic pharmaceutical industry, supported by complementary policies and financing.

The post-1970 patent regime and the transitional period without product patent protection permitted India to develop a thriving pharmaceutical industry and to become a major supplier of pharmaceutical products domestically and globally (including low-cost active pharmaceutical ingredients). This also created conditions for some of the companies in the industry to growingly invest in research and development.⁸⁴

The amendment of India's Patents Act to enable India to implement the TRIPS Agreement from 1 January 2005 went through intensive and difficult public debate. At the centre of the debate was the maximization of TRIPS flexibilities. The amended law retains several important flexibilities even

82 *Economist*, 27 May 1995 (Asia edition)

83 Article 66.1 of the TRIPS Agreement; Doha Declaration on the TRIPS Agreement and Public Health (2001), paragraph 7.

84 Report of the WHO Commission on Intellectual Property, Innovation and Public Health (2006) at pages 83-84 <http://www.who.int/intellectualproperty/documents/thereport/CHPublicHealthReport.pdf>

though India must now allow for patents on pharmaceutical products. However, India has also lost considerable policy and legal autonomy and the future of India as a major generic medicines supplier, especially to developing countries, is uncertain. This means that the potential role of China as a generic producer of finished pharmaceutical products and active pharmaceutical ingredients becomes more important.

D.1 Striking a balance in the TRIPS Agreement

The introduction of intellectual property rights into the negotiations of trade agreements called the Uruguay Round (1986-1994) was very controversial with most developing countries objecting to such a move. In the end, as part of a compromise package of agreements, the TRIPS Agreement was accepted. Even though the freedom of individual countries to formulate their own patent or other intellectual property system was reduced, the fundamental concept of the need of balance of rights and interests was retained.

Thus the TRIPS Agreement recognizes that “intellectual property rights are private rights”. It also recognizes “the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives” (Preamble).

Article 1 of the TRIPS Agreement states that “Members may, **but shall not be obliged to**, implement in their law more extensive protection than is required by this Agreement ... Members **shall be free** to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice ...”⁸⁵

Article 7 on Objectives states that: “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology knowledge and in a **manner conducive to social and economic welfare, and to balance of rights and obligations**”.⁸⁶

Article 8 on Principles states that:

“1. Members may, in formulating or amending their laws and regulations, **adopt measures necessary to protect public health and nutrition**, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to **prevent the abuse of intellectual property rights by the right holders** ...”⁸⁷

Many of the exclusions, limitations and exceptions available in patent law are maintained in the operational provisions of the TRIPS Agreement even though a considerable degree of national policy space to design country-specific IP systems is given up when a country becomes a WTO Member. However, it is now generally recognized that the current system of patent protection based on the TRIPS Agreement and the ‘TRIPS-plus’ demands from developed countries have major impacts on the generic pharmaceutical sector and thus access to affordable pharmaceutical products. This makes the pro-public health interpretation of the TRIPS Agreement flexibilities, such as parallel imports and compulsory licenses, even more important.

The impact of patents on the prices of medicines was felt soon in developing countries that introduced pharmaceutical patent protection as a result of the TRIPS Agreement or prior to its

⁸⁵ Emphasis added.

⁸⁶ Emphasis added.

⁸⁷ Emphasis added.

entry into force. But the alarm really went off with the high prices of HIV medicines and the moves by some major companies and developed countries' governments to block TRIPS-compatible measures aimed at obtaining cheaper ARVs for HIV treatment. The case of the legislation passed in South Africa – challenged by a group of multinational corporations and the US government – was emblematic in this regard⁸⁸. The tension between the TRIPS Agreement and public health led a number of developing countries, actively supported by civil society groups (international and national) to seek the clarification of the room still available under said Agreement to protect public health as finally. This was the purpose of the Doha Declaration adopted by the 4th WTO Ministerial Conference in 2001⁸⁹.

The Declaration recognized “the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics” (paragraph 1).

The Declaration stressed “the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems” (paragraph 2).

While recognizing that “intellectual property protection is important for the development of new medicines”, the Declaration also recognizes “the concerns about its effects on prices” (paragraph 3).

It was agreed that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health” and accordingly while the commitment to the TRIPS Agreement was reiterated, the Declaration “affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all” (paragraph 4).

In this connection, the Declaration “reaffirm(ed) the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose” (paragraph 4).

It is important to note that the Doha Declaration did not create any new rights but reaffirmed what was already in the TRIPS Agreement.

Although HIV, tuberculosis and malaria and other epidemics were highlighted, there are no limits on the types of diseases in the Doha Declaration. Thus governments are not restricted to any diseases when it comes to ensuring affordable essential medicines for their citizens.

Two influential reports emphasized the crucial importance of the TRIPS Agreement flexibilities for developing countries:

- Integrating Intellectual Property Rights and Development Policy – Report of the Commission on Intellectual Property Rights, established by the United Kingdom (2002)⁹⁰; and
- Report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health (2006)⁹¹.

88 See, e.g., Ellen t’Hoen, *TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, available at <http://www.who.int/intellectualproperty/topics/ip/tHoen.pdf>.

89 On the impact of the Doha Declaration, see C Correa and D Matthews, *The Doha Declaration ten years on and its impact on access to medicines and the right to health. Discussion Paper*, UNDP, New York, 2011.

90 www.iprcommission.org For the Chinese version of the report see: http://www.iprcommission.org/graphic/Chinese_Intro.htm

91 <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf> For the Chinese version of the report see: <http://www.who.int/intellectualproperty/documents/thereport/CHPublicHealthReport.pdf>

The two commissions comprised international experts on intellectual property, development and public health. The originator pharmaceutical sector also had representatives in these Commissions.

The UK Commission cautioned countries “to ensure that their intellectual property protection regimes do not run counter to their public health policies and that they are consistent with and supportive of such policies”.

The WHO Commission report concluded that while intellectual property is supposed to encourage innovation, there is a lack of research for developing new treatment tools, including medicines, diagnostics and vaccines needed to address the diseases prevailing in developing countries. The report provided several recommendations aiming to promote the development of a health-driven medical R&D incentive framework, and to increase access to medicines for poor populations in developing countries.⁹² It highlighted the need for developing countries to make full use of the TRIPS flexibilities, weighing the needs of public health in every case. The Commission also cautioned that bilateral trade agreements should not seek to incorporate TRIPS-Plus protection in ways that may reduce access to medicines in developing countries.⁹³ This is a trend that has raised widespread concerns in recent years.

Following the report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health, an Inter-governmental Working Group (IGWG) open to the participation of all WHO Members was set up. After protracted negotiations, a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property was adopted by the World Health Assembly through Resolution 61.21 in 2008.⁹⁴ Actions foreseen under this Global Strategy and Plan of Action

The adopted Global Strategy agreed on undertaking actions, *inter alia*, to

- Promote active and effective participation of health representatives in intellectual property-related negotiations;
- Provide as appropriate upon request in collaboration with other competent international organizations technical support to countries that intend to make use of TRIPS flexibilities;
- Take into account where appropriate the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by TRIPS (TRIPS plus);
- Encourage finding ways in ongoing discussions, to prevent misappropriation of health-related traditional knowledge and consider where appropriate legislative and other measures to prevent misappropriation;
- Explore and promote a range of incentives for R&D including addressing where appropriate the de-linkage between the costs of R&D and the price of health products.
- Support the production and introduction of generic version in developing countries, through the development of national legislation and/or policies that encourage generic production and entry including a regulatory exception or Bolar type provision⁹⁵;
- Frame and implement policies to improve access to safe and effective health products;

⁹² Ibid.. at pages 175-188.

⁹³ Ibid. at page. 130

⁹⁴ http://www.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf

⁹⁵ The ‘Bolar exception’ is discussed in Section E.

- Consider where necessary taking appropriate measures to prevent the abuse of IP by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology⁹⁶.

China participated in the WHO process that adopted the Global Strategy and Plan of Action, whose implementation would be complementary to implementing TRIPS flexibilities at the national level.

E IMPLEMENTING TRIPS FLEXIBILITIES IN CHINA

China's government is aware of the importance of an intellectual property system that strikes a right balance between public rights and private interests, between incentives for innovation and the need to prevent abuse of exclusive rights.

From 2005 onwards, two important national processes were in place: the formulation of the *National Intellectual Property Strategy* and the third revision of the *Patent Law*. For both processes considerable research and studies were conducted, both on macro issues and on specific sectors and topics. There was solicitation of views from various sectors including from the public. International public interest groups, the foreign private sector and foreign governments were also free to submit their views.

China has long been a target for the industries and governments of developed countries, especially the US, who have sought to ensure 'high standards' for the protection and enforcement of intellectual property rights in China.

China had lost room for manoeuvre since the early 1990s when it entered into its first bilateral IPR agreement with the US and continued to make more concessions in the bilateral negotiations with the US and other developed countries in order to be accepted to join the WTO.

Bilateral IPR agreements between China and the US were negotiated in 1992, 1995 and 1996. The biggest concession was allowing for product pharmaceutical patents since 1992 when there was no international obligation to do so. Related to this was the retrospective granting of 7.5 years exclusivity through 'Administrative Protection' by SFDA, for drugs that were patented abroad, but not in China, between 1 January 1986 and 1 January 1993. By the time China joined the WTO in 2001 after nearly 15 years of WTO accession negotiations, China had agreed to a number of 'TRIPS-plus'⁹⁷ obligations.

A Joint Commission on Commerce and Trade (JCCT) was established in 1983 as a forum for high-level dialogue on bilateral trade issues. In 1994, as US-China commercial relations became increasingly complex, the two governments institutionally strengthened the JCCT by establishing 10 structured working groups covering a range of topics including IPR. These were in addition to a side dialogue on export controls. From its inception until 2004, the JCCT was co-chaired by the US Secretary of Commerce and China's Minister of Commerce. Following the December 2003 meeting of President Bush and Premier Wen Jiabao, the two sides agreed the Commission would be co-chaired on the US side by two cabinet officials (the Secretary of Commerce and the US Trade Representative) and, on the Chinese side, by the Vice Premier responsible for foreign trade. In the

⁹⁶ See Elements 5 and 6.

⁹⁷ 'TRIPS-plus' refers to obligations and standards of IPR protection that exceed the requirements of the TRIPS Agreement.

November 2004, July 2005 and April 2006⁹⁸ meetings of the JCCTa China agreed to high-level IPR enforcement commitments, in addition to China accepting more obligations in the copyright field.

China officially became a WTO Member the year the Doha Declaration was adopted, and participated actively in the WTO TRIPS Council to work out a solution to an outstanding problem identified by Members in the Doha Declaration: the obstacle to access to medicines created by Article 31(f) that restricts the products manufactured under a compulsory licence to be predominantly for the supply of the domestic market of the country where the licence was issued. As discussed below (section E.3.5), negotiations succeeded in producing waivers to two provisions of the TRIPS Agreement and, later on, a proposal for amending the TRIPS Agreement⁹⁹.

At a symposium co-organized by the Ministry of Commerce, the Ministry of Health and the State Intellectual Property Office (SIPO) on 10 June 2008, Vice-Minister of Commerce Yi Xiaozhun said in the opening plenary:

“...The Chinese government has been actively involved in the negotiation of TRIPS Agreement and Public Health, and has firmly held that the TRIPS Agreement should strike a balance between intellectual property protection and public rights protection. Interestingly, the pharmaceutical sector chose not to have its interests asserted in this complaint.”

Awareness has increased in China among policy makers and regulators, patent examiners, researchers, the HIV community, relevant NGOs and the domestic pharmaceutical companies about the importance of TRIPS flexibilities for the production and distribution of generic medicines, and for ensuring access to affordable ARVs and other essential medicines. For instance, at the same symposium mentioned above, Deputy Commissioner of SIPO, Li Yuguang, said:

“... the grant and protection of the exclusive rights (of patent) is not the ultimate goal of the patent system. The real purpose ... is to stimulate innovation and invention and promote scientific and technological progress. From this angle, we should reasonably balance the relationship between patent right holder's exclusive rights and the public interests. No bias should be allowed. While strengthening patent protection, we should prevent damage to just public interests caused by the improper exercise of patent rights. If we allow patent right holders to abuse their exclusive rights, directly preventing the vast patients who are suffering from diseases and even facing the threat of death from gaining medicine to survive, we are going counter to the goal of our IP system. In this sense, we should immediately adopt effective measures, bring the active roles of patent protection into full play, and eliminate the negative influences brought by patent rights abuse, exploring more feasible plans to resolve public health problems and increase access to medicines, and promoting the harmony and balance between IPR protection and public interests maintenance.

The system of Compulsory Licensing of Patent Implementation is an important measure to prevent exclusive rights abuse and maintain public interests. In simple words, under the legal conditions, the state governmental departments can authorise a third party to exercise some certain patented technologies according to law even without authorisation from the patent right holders.”

E.1 China's National Intellectual Property Strategy

On 5 June 2008 China's *National Intellectual Property Strategy* was publicly announced. It is significant that public health has been highlighted, and running through the public document is

⁹⁸ These have continued since then to the present with higher patent protection/enforcement and data protection for drug registration as recurring topics.

⁹⁹ The amendment has not obtained yet the minimum number of Members' approvals necessary to become operative.

the recognition of the need to develop an IP system that suits the needs of the country. This would require maximizing the TRIPS Agreement flexibilities.

In January 2005, the State Council approved the establishment of the Leading Group for the National Intellectual Property Strategy Formulation headed by Wu Yi, then deputy premier of the State Council. Ministers from almost 30 ministries were members of the Leading Group that was in charge of making decisions on important issues that come up during the course of the strategy-formulation process. Such issues included the orientation of the national IP strategy, the guiding ideology and work scheme of the strategy formulation, the overall planning and coordination of strategy, and the examination and approval of all final research results.

The National IP Strategy Office (NIPSO) worked under the Leading Group, and was responsible for undertaking the day-to-day routine work. The agency is located in SIPO. Its main duties included: putting forward suggestions about the implementation of the strategy-formulation work, undertaking day to day work assigned by the Leading Group, monitoring the implementation of the decisions made by the Leading Group, coordinating national intellectual property strategy-related matters among related ministries.

China is one of the few developing countries that have formulated a national intellectual property strategy, and it has done so through a transparent process that involved a wide range of ministries, numerous studies (both macro issues and research on specific sectors and industries) and consultations within the country and with foreign experts. Inputs from the domestic and international public health community on access to affordable essential medicines were also a contribution to the Strategy formulation.¹⁰⁰ Several visits were also made to the patent offices in the Brazil, India, Japan, Europe and the US.

There were four phases in the formulation process: the preparation phase, the substantial research phase, public opinion and comments-soliciting phase and the final phase. In 2006, when most of the research groups had concluded their substantial research work, comments were solicited from related government agencies, enterprises and others.

There was considerable interest in international IP experiences and listening to the opinions and suggestions of other countries on national intellectual property strategy formulation work. On 12 January 2006, NIPSO held a meeting to solicit comments on China's National Intellectual Property Strategy Formulation Work from foreign embassies in Beijing. On 23-24 February 2006, an international seminar was held in Beijing.¹⁰¹ This was followed on 13 July 2006 with a meeting to listen to opinions and suggestions from foreign enterprises in China. NIPSO also established a specific governmental website to disseminate related information and collect views and opinions from people of various circles.

The main contents of the national IP strategy include not only analysis of macro issues such as the impact of IP on economic and social development but also some case studies of some typical industries that are mostly influenced by IP. It comprises a general outline part and a special topics part. The national intellectual property strategy outline is intended to guide China's IP work in the next 15 to 20 years. It is formulated to facilitate the implementation of three national strategies (Strategy of Revitalizing the Nation through Science and Education, the Strategy of Building a Powerful Nation Based on Talents, the Strategy of Sustainable Development) and to provide

100 Discussions involving TWN. MSF, NIPSO and SIPO officials in 2007-2008.

101 TWN was invited to present a paper on "Intellectual Property and Development". On 2 February 2007, TWN participated in a one-day dialogue with NIPSO. The meeting was chaired by Dr. Zhang Qin (then Deputy Director of NIPSO and Deputy Commissioner of SIPO) and attended by a number of senior officials and the drafting team of the Strategy. The topics included the philosophical and systemic issues related to IP and development, public health, biological resources and traditional knowledge, access to information, research and innovation as well as technology transfer.

strong support for the realization of the goal to elevate China to the status of an innovation-based country.¹⁰²

The outline was adopted by the State Council and publicly released on 5 June 2008 as the 'Compendium of China National Intellectual Property Strategy'.¹⁰³ The Strategy consists of 20 special topics and one Compendium, which is based on the early-stage research outcomes on the 20 special topics. While implementing the strategy, the Central Government "will not only stimulate the working enthusiasm of various departments of the Central Government, but also stimulate the zeal of local governments, guilds, enterprises, institutions and the whole people. We will formulate our blueprint and working plans and after working out the blueprint and plans, assign different goals to related departments according to the plans so as to promote the implementation gradually"¹⁰⁴.

A review of the Compendium shows that there are crucial opportunities for improving China's IP system to promote public health, in particular access to affordable essential pharmaceutical products. Paragraph 2 states:

"Intellectual property system is a basic system for developing and utilizing knowledge-based resources. By reasonably determining people's rights to certain knowledge and other information, the intellectual property system adjusts the interests among different groups of persons in the process of creating and utilizing knowledge and information, encourages innovation and promotes economic and social progress. In the world today, with the development of the knowledge-based economy and economic globalization, intellectual property is becoming increasingly a strategic resource in national development and a core element in international competitiveness ... The international community attaches greater importance to intellectual property as well as innovation. Developed countries take innovation as the main impetus driving economic development, and make full use of the intellectual property system to maintain their competitive advantages. Developing countries actively adopt intellectual property policies and measures suitable for their respective national conditions to promote development".

Under the section on "Specific Focus" there are relevant paragraphs for public health concerns:

"Improving IP regime"

(8) ... Intellectual property-related provisions contained in laws and regulations concerning unfair competition, foreign trade, science and technology and national defense need to be improved.

(10) The guiding role of intellectual property in economic, cultural and public policies needs to be strengthened. More efforts need to be adopted to improve coordination between intellectual property policy and the policies of industry, region, science and technology and trade ... Coordination and uniformity between intellectual property policy and policies of culture, education, science and health need to be strengthened to safeguard the right of the public to legally and rationally utilize innovation findings and information in their cultural, educational, scientific and public health activities, promote the fair sharing of innovation and information, and ensure that the government is able to deal with public crises.

102 http://english.ipr.gov.cn/ipr/en/info/Article.jsp?a_no=11675&col_no=102&dir=200608

103 http://www.sipo.gov.cn/sipo_English/news/iprspecial/200806/t20080612_406418.htm

104 Interview on the Chinese Central Government Web Portal (24 June 2008) with Dr. Zhang Qin, Deputy Commissioner of SIPO, who chaired the drafting team of the National IP Strategy. http://www.sipo.gov.cn/sipo_English/news/official/200807/t20080703_409820.htm

“Preventing Abuses of IPRs”

(14) Formulate relevant laws and regulations to reasonably define the scope of intellectual property. Prevent abuses of intellectual property. Maintain fair market competition. Safeguard the public lawful rights and interests”

Under the section on “Specific Tasks” with regard to patent:

(16) Make advanced development plans according to the nation’s strategic needs in some sectors such as biology, medicine, information, new materials, advanced manufacturing, new energy, oceanography, resources, environmental protection, modern agriculture, modern transportation, aeronautics and astronautics, and to obtain a group of patents in these core areas of technology to support the development of China’s new and high technology industries.

(19) Improve the patent examination procedure and the quality of examination according to the requirements for granting patents. Irregular patent applications need to be prevented.

(20) Balance the need for patent protection and the need to protect public interest properly. While strengthening patent right protection in accordance with law, we need to improve the compulsory licensing system and make good use of exception provisions. We need to work out relevant policies that are rational to ensure that the public is able to obtain necessary products and services in a timely and sufficient manner whenever a public crisis happens”.

With regard to “Strategic Measures”, the Compendium states the following:

“Expediting the Development of the Legal System for Intellectual Property”

(44) Establish a legislation mechanism in line with the characteristics of intellectual property, improve the quality of legislation and speed up the legislation process. Improve foresight studies before intellectual property legislation is formulated and the assessment work after enactment. Legislation needs to be more transparent, and more channels need to be available for enterprises, industrial associations and the public to participate in legislation. Revisions and legislative interpretations of intellectual property laws need to be improved in order to deal with new problems in the intellectual property sector promptly and effectively. Studies on the necessity and feasibility of formulating basic intellectual property laws need to be carried out

“Strengthening the Administration of Intellectual Property”

(53) Set up an intellectual property early-warning and emergency-response system. Issue report on intellectual property development trends in important sectors and work out contingency plans for disputes, conflicts or emergency situations on intellectual property that have a wide-ranging and significant impact, so that they can be dealt with in proper way and any potential damage can be controlled or reduced”

The Strategy also recognizes that “China needs to actively participate in the development of international intellectual property order and effectively involve itself in undertakings of international organizations” (paragraph 66).

Thus, China’s National IP Strategy represents an important effort to balance private rights and public interests. A new department was established in SOIPO to support the implementation of the Strategy.

E.2 Patent ownership in China

There has been an impressive growth of patent applications and grants in the last decade in China. Patent grants increased by 28.80 percent in 2000-2006, with a slightly higher rate for foreign owned patents (30.90 percent against 26.30 percent of domestic patenting)¹⁰⁵. 92,867 invention patents were granted in this period for domestic applicants and 155,190 to foreign applicants¹⁰⁶. In 2011 alone, SIPO granted 172,000 invention patents, up by 27.4 percent from the previous year; 112,000 (65.1 percent) were granted to domestic applicants and 60,000 (34.9 percent) to foreign applicants¹⁰⁷.

On 1 October 1993, China acceded to the Patent Cooperation Treaty (PCT) which entered into force in the country on 1 January 1994. This was also part of the obligation under the 1992 bilateral IPR agreement with the US.

The PCT makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing an 'international' patent application. Such an application may be filed by anyone who is a national or resident of a PCT contracting State. It may generally be filed with the national patent office of the contracting State of which the applicant is a national or resident or, at the applicant's option, with the International Bureau of the World Intellectual Property Organisation (WIPO) in Geneva.¹⁰⁸ As a receiving office of the PCT, SIPO received a total of 17,473 PCT applications in 2011, up 35.3 percent from the previous year¹⁰⁹. In 2011, SIPO received 66,320 PCT applications that entered China's national phase, up 6.0 percent year on year, among which 65,996 were invention patents applications and 324 were utility model applications. Since 1994, SIPO had received a total of 541,009 PCT applications that entered China's national phase¹¹⁰.

In 2011, the largest number of patent applications classified by sector received by SIPO related to pharmaceuticals.¹¹¹ Although specific data is not available, the percentage of pharmaceutical patents can be expected to be even much higher for foreign patent holders compared to domestic patent holders. Certainly, the patents on ARVs are almost exclusively held by foreign entities.

There is a noticeable proliferation of patent applications and grants in the pharmaceutical field. Large numbers of applications on developments with no or low inventive step are often filed. This trend should be of concern to the various relevant government authorities, as there are serious implications for China's development prospects in terms of research and innovation, as well as for access to essential products such as affordable pharmaceutical products.

E.3 China's Patent Law and Implementing Regulations

The Patent Law of China was adopted on 12 March 1984 and entered into force on 1 April 1985. It was revised in 1992, 2000 and 2008.¹¹² Under the Patent Law of 1984, no patents could be granted for:

- Methods for the diagnosis or for the treatment of diseases;

105 See http://english.sipo.gov.cn/statistics/200804/t20080416_380892.html.

106 See http://www.sipo.gov.cn/sipo_English/statistics/200706/t20070611_174614.htm.

107 See <http://english.sipo.gov.cn/laws/annualreports/2011/201207/P020120731383147261128.pdf>.

108 For a summary of the PCT see: http://www.wipo.int/treaties/en/registration/pct/summary_pct.html

109 See <http://english.sipo.gov.cn/laws/annualreports/2011/201207/P020120731383147261128.pdf>.

110 See 2011 SIPO Annual Report, available at <http://www.lilon.com/ipdata/SIPO%20Annual%20Report%202011.pdf>.

111 See <http://english.sipo.gov.cn/laws/annualreports/2011/201207/P020120731383147261128.pdf>.

112 See http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119_566244.html

- Pharmaceutical products or substances obtained by chemical processes.

However, the process of making of pharmaceutical products or chemical materials was patentable.

In 1992, following the first bilateral IPR agreement with the United States, there was a revision of the Patent Law repealing the exclusion of patents on pharmaceutical products and substances. By so doing, China that was in the midst of a long negotiation process to join the WTO, prematurely allowed product patents. As mentioned, Members of the WTO that were developing countries had a right not to allow for pharmaceutical product patents until 1 January 2005 if they did not grant them at the time the TRIPS Agreement entered into force for them.

A third revision of the Patent Law was undertaken in 2006. A draft for Patent Law Amendment was submitted by SIPO to the State Council on 27 December 2006. After several rounds of discussions at the State Council and the Standing Committee of the 11th National People's Congress, the amendments were adopted on 27 December 2008, entering into force on 1st October 2009. The third Patent Law revision was undertaken in parallel with the formulation of the National IP Strategy, both of which entailed considerable research and analysis as well as a wide solicitation of domestic and international views and inputs.

Meanwhile, in February 2007 SIPO also started the process to amend the Implementing Regulations of the Patent Law that is within SIPO's mandate. In December 2007, 21 project teams submitted their research reports in relation to 16 important issues, including the improvement of legislation on compulsory licensing. In March 2008 the Legal Affairs Department of SIPO completed the preliminary draft of the revised Regulations to be aligned with the revised Patent Law. The Patent Examination Guidelines of 2006 were revised in 2010.

The revisions adopted in 2008 related to public health were aimed at increasing the use of TRIPS flexibilities. They are discussed in the following sub-sections.

E.3.1 Scope of patentability/exclusions from patentability

The Patent Law uses the term 'invention-creations' to refer to inventions, utility models and designs (Article 2). 'Inventions' mean new technical solutions proposed for a product, a process or the improvement thereof. Pharmaceutical products and processes and improvements thereof can be patented under the Patent Law as inventions for 20 years from the date of application, upon a successful examination. A utility model or design can be protected for 10 years from the date of application (Article 42).

No patent right shall be granted for any invention that violates the law or social ethics, or harms public interests (Article 5).

In addition, Article 25 of the Law lists out exclusions from patentability:

- scientific discoveries;
- rules and methods for intellectual activities;
- methods for the diagnosis or for the treatment of diseases;
- animal or plant varieties¹¹³;
- substances obtained by means of nuclear transformation.

¹¹³ Processes for producing animal or plant varieties may be patented.

E.3.2 Patentability Criteria and Examination of Patent Applications

An important flexibility under the TRIPS Agreement is the right of WTO Members to define the patentability criteria under Article 27.1 in accordance with their particular national priorities. Article 27.1 of the TRIPS Agreement states that patents “shall be available for any inventions ... provided that they are new, involve an inventive step and are capable of industrial application”. However there is no requirement on how these criteria are to be applied. WTO members can thus adopt their own definitions of the patentability standards.

Appropriate patentability standards may be an important tool for the promotion of genuinely new and inventive pharmaceutical products, and to ensure access to affordable essential medicines. A common belief is that patents are normally granted to protect new medicines, but while the number of patents annually obtained to protect genuinely new pharmaceutical products is small and declining, thousands of patents are granted for pharmaceuticals. A large number of patents cover minor modifications of older existing drugs¹¹⁴.

The general terms used in TRIPS Article 27.1 have permitted WTO Members to keep different criteria to assess patentability. The definition of such criteria constitutes a key aspect of patent policy, with implications in other areas, such as industrial and public health policies. The narrower the novelty standard, the lower the bar to assess inventive step, and the broader the concept of industrial applicability or utility, the greater the number of applications that may be granted in a particular country. A greater number of grants made on the basis of low standards of patentability may lead to unnecessary limitations on competition without benefit to society.¹¹⁵

Article 22 of China’s Patent Law sets out the requirements for granting a patent, whereby the invention or utility model must ‘possess the characteristics of novelty, inventiveness and usefulness’.

Novelty means that the invention does not form part of the prior art including published patent applications filed with SIPO by any unit or individual for any identical invention.

Inventiveness means that, as compared with the prior art, the invention has prominent substantive features and represents a notable progress.

Usefulness means that the invention can be made or used and can produce effective results.

Under the Patent Law, China applies a substantive examination system. The 2001 SIPO Guidelines for Examination (revised in 2006 and 2010) develop the provisions of the Patent Law and its Implementing Rules.

The Patent Office makes decisions on applications, on behalf of SIPO. The Patent Review Board, set up by SIPO, is responsible for examining requests for re-examination and requests for invalidation and for making decisions accordingly.

Some of the grounds for rejecting a patent application are as follows:

- The invention does not fall under the definition of invention.
- The invention violates the law or social ethics, or harm public interests, according to article 5 of the Patent Law.

114 C Correa, *Guidelines for the examination of pharmaceutical patents: Developing a public health perspective* (2007), WHO-ICTSD-UNCTAD-UNDP, Geneva.

115 Ibid.

- The subject matter of the application is excluded under Article 25, such as scientific discoveries, rules and methods for intellectual activities and methods for the diagnosis or for the treatment of diseases.
- The invention lack novelty, inventiveness, or usefulness.
- The description of an invention is not sufficiently clear and complete.
- The claims are neither sufficiently clear, nor concise nor technically convincing to solve a certain technical problem.
- Another applicant has applied for the same patent already.

The Patent Law further provides for review when a patent application is rejected and where a granted patent is challenged. Under Article 41 of the Patent Law, "The patent administration department under the State Council shall establish a patent review board. If a patent applicant is dissatisfied with the decision made by the Patent Administration Department under the State Council on rejecting of the application, he may, within three months from the date of receipt of the notification, file a request with the patent review board for review. After review, the Patent Review Board shall make a decision and notify the patent applicant of the same. If the patent applicant is dissatisfied with the review decision made by the patent review board, he may take legal action before the people's court within three months from the date of receipt of the notification."

Under Article 46, "The patent review board shall examine the request for declaring a patent right invalid and make a decision in a timely manner and notify the requesting person and the patentee of its decision. The decision on declaring a patent right invalid shall be registered and announced by the patent administration department under the State Council. A person that is dissatisfied with the patent review board's decision on declaring a patent right invalid or its decision on affirming the patent right may take legal action before a people's court, within three months from the date of receipt of the notification. The people's court shall notify the opposite party in the invalidation procedure to participate in the litigation as a third party."

One example of the way in which the system works is provided by GSK's patent application for a tablet formulation of lamivudine and zidovudine (brand name of Combivir), which was rejected by the Patent Re-examination Board (as it was called before the 2008 Law amendments). This was actually a claim over a combination of previously known active ingredients. The application had been originally rejected in August 2004. An appeal was made by GSK. After the re-examination process, the Board reached a decision, at the end of 2006, not to grant the patent on the ground that it did not fulfil the patent examination criteria. It is interesting to note that GSK had announced during the world HIV conference in 2006, that it would withdraw Combivir patents world-wide. However, information from SIPO showed that during the whole process of patent examination and re-examination, GSK never requested to withdraw its patent application in China.¹¹⁶

Although there was no product patent on Combivir in China, there was 'Administrative Protection' from the SFDA conferring exclusivity on lamivudine (3TC) until October 2006. As discussed above in Section B, GSK continued to assert that one of its then existing process patents was broad enough to cover products containing 3TC. This continued to prevent domestic production or import of generic 3TC until 2011. Though there was ultimately a successful challenge to the GSK patent in late 2010 the period between this and the expiry of the questionable patent was very short.

¹¹⁶ Communication from MSF in 2007.

E.3.3 Compulsory license, including “Government Use”

Compulsory licensing is an important tool when a patent leads to inadequate access to affordable pharmaceutical products. In accordance with the TRIPS Agreement, a government can issue a compulsory license on grounds to be determined by national law. The Doha Declaration reaffirms “the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement which provide flexibility” which includes “the right to grant compulsory licenses and the freedom to determine the grounds upon which such licences are granted”.

Where a non-government party seeks to import or manufacture or sell a patented product, they have to first negotiate a voluntary licence with the patent holder. Upon failure to negotiate a voluntary licence on reasonable terms within a reasonable time, an application can be made to the government to obtain a licence for the compulsory or non-voluntary use of a patent and the patent holder will have to abide by such an order.

However, Article 31 of the TRIPS Agreement does not require prior negotiation with the patent holder to obtain a voluntary license before a government authorises a compulsory licence, in various cases, such as:

- A national emergency or other circumstances of extreme urgency; or
- To remedy a practice determined by a judicial or administrative process to be anti-competitive.

Similarly, in cases of public, non-commercial use (commonly referred to as “Government Use”), there is no obligation to engage in prior negotiations with the patent owner.

The Doha Declaration further reaffirms that: “Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency”.

However, it is very important for WTO Members to know that there can be other public interest grounds for granting a compulsory license in addition to “national emergency or other circumstances of extreme urgency”, such as lack or insufficient exploitation of the invention and excessive pricing.

In each case of a compulsory license, including Government Use, there is a need for adequate remuneration to be paid to the patent holder.

China’s current Patent Law has three main provisions (Articles 48 to 50) on compulsory licensing¹¹⁷ that are relevant for promoting access to affordable pharmaceutical products.

In order to standardize the procedures for granting such licenses, including the content and the hearing of the request, the *Measures on the Compulsory Licence for Exploitation of a Patent* were promulgated in 2003.

The 2003 Measures have been revised to be in line with the latest (2008) amendments made to the Patent Law and Implementing Regulations. In 2011 the public was invited to provide comments and consultation meetings were held with relevant government bodies, domestic and international NGOs and private companies. Since compulsory licensing applies to all processes and products, consultations also covered non-public health related fields. The *Measures for Implementation of*

¹¹⁷ Only patents on inventions and utility models can be subject matter of compulsory licenses, not designs.

Compulsory Licensing of Patents were issued as SIPO Order No.64 on **15 March 2012** and entered into force on 1st May 2012¹¹⁸.

Article 48 of the Patent Law provides that: “Under any of the following circumstances, the patent administration department under the State Council (i.e. SIPO) may, upon application made by any unit or individual that possesses the conditions for exploitation, grant a compulsory license for exploitation of an invention patent or utility model patent:

(1) When it has been three years since the date the patent right is granted and four years since the date the patent application is submitted, the patentee, without legitimate reasons, fails to have the patent exploited or fully exploited; or

(2) The patentee’s exercise of the patent right is in accordance with law, confirmed as monopoly and its negative impact on competition needs to be eliminated or reduced.”

This is one of the provisions that a manufacturer of generic pharmaceutical products could invoke to obtain an authorization to exploit a patented pharmaceutical product or process.

Article 49 of the Patent Law provides that:

“Where a national emergency or any extraordinary state of affairs occurs, or public interests so require, the Patent Administration Department under the State Council (SIPO) may grant a compulsory licence for exploitation of an invention patent or utility model patent”.

Article 49 covers situations of “national emergency or other circumstances of extreme urgency” as well as “public non-commercial use” (Government Use) under the TRIPS Agreement. The competent department under the State Council can make a request to SIPO for a compulsory license.¹¹⁹ In the case of medicines, it would be the Ministry of Health and there is no requirement for a hearing of the patent holder as in the case of a compulsory license request under Article 48. There is no need to have prior negotiations with the patent holder either.

SIPO may, as suggested by a competent department under the State Council, directly grant a compulsory licence to the entity designated by the department. This would allow, for example, the MOH to designate a generic manufacturer as the entity to be granted the compulsory licence to manufacture selected ARVs.

Article 12 of the 2012 Measures requires that when the competent department under the State Council asks for a compulsory licence under Article 49 of the Patent Law, it shall indicate the following:

(i) Name and address of assigned entity with capacity obtaining the compulsory licensing for patent implementation;

(ii) The name, patent number, patentee, date of application and date of authorized announcement of the invention patent or patent of utility models relating to the petitioned compulsory licensing;

(iii) The term required for compulsory license.

During the 2011 consultations conducted by SIPO, a submission by MSF pointed out that in most countries the law requires the naming of the generic product rather than the details of every patent that may be linked to the product. Thus the details required in (ii) above would be cumbersome – if a medicine has multiple patents (including process patents) the burden is on

118 See http://www.sipo.gov.cn/zwgs/ling/201203/t20120319_654876.html.

119 Article 6, Measures for Compulsory Licensing of Patent Implementation (2012).

the generic manufacturer to conduct a full search of the relevant patents. A preferable alternative would have been just the generic names of the medicines concerned as in the law and practice of Indonesia and Malaysia.

Although China has had a compulsory licensing legal system in place for many years there has not been any licence requested yet. SIPO officials have reiterated that this is an important tool and are very supportive of its use. As noted above, SIPO Deputy Commissioner Li Yuguang said in 2008: "The system of Compulsory Licensing of Patent Implementation is an important measure to prevent exclusive rights abuse and maintain public interests".¹²⁰

There have been two proposals calling for compulsory licensing of ARVs, submitted to official bodies.

In March 2006, a proposal from Dr. Shao Yiming (chief scientist at the National Centre for AIDS and a virologist) was submitted to the China People's Political Consultative Congress (CPPCC). Dr. Shao himself was a member of the CPPCC.

The proposal contained the following suggestions:

- that MOH immediately organize experts to research and establish a list of urgently needed, patented anti-AIDS antiretroviral drugs in China.
- that MOH start the procedure of compulsory licensing of generic drugs as soon as possible, according to the Chinese law and the relevant procedures of the WTO decision.
- that SFDA assist manufacturers to undertake production and grant registration as soon as possible.
- that relevant sections of the country provide technical support to generic manufacturers in order to acquire approval from the WHO, so that they can enter the international generic drug market.
- that the Ministry of Commerce and Ministry of Foreign Affairs, through China's commercial and diplomatic channels, help African countries to acquire generic drugs made in China for patients' use. China should consider anti-AIDS drugs as part of its other aid activities for Africa.

On 14 March 2008 a civil society "Proposal about Improving Drug Registration Process, Modifying Relevant Provisions and Ensuring ARV Supply" was mailed to the National People's Congress, the National Committee of the CPPCC and the Ministry of Health. The proposal was made by Thomas Cai (Head of AIDS Care China) and Wan Yanhai (Director of Aizhi Institute, who represented the concerns of the hepatitis B community). It highlighted the control of ARV patents by foreign pharmaceutical companies and the delay in the availability of tenofovir (TDF) and lamivudine, the latter being an essential drug for both the AIDS and hepatitis B communities. The proposal requested, among other things, a "further revision of the Patent Law and its implementation provision and to adopt more of the flexibilities in the International Treaty (TRIPS) that is beneficial to China while China carries out its obligation at the WTO". Such a move would "protect the right of Chinese citizens to life and health and reduce the financial burden of the Chinese People".

Since 2010 there have been some indications from the MOH at a high level that compulsory licensing is an option for consideration. In line with the ongoing health reform in the country, a revision of the essential medicines list has taken place and, as seen from the above discussion in Section B, China's national response to the HIV epidemic has been progressing significantly on

120 Opening plenary, International Symposium on TRIPS and Public Health, Beijing, 10 June 2008. Organized by the Ministry of Commerce, the Ministry of Health and the State Intellectual Property Office.

several fronts. Nevertheless, patents are still an obstacle to access to affordable ARVs and other essential medicines.

E.3.4 Implementation of the WTO Decision under Paragraph 6 of the Doha Declaration ('30 August Decision')

An obstacle to the full use of compulsory licensing is Article 31(f) of the TRIPS Agreement that restricts the products manufactured under a compulsory license to be “predominantly for the supply of the domestic market” of the WTO Member authorizing the license.

The Doha Declaration in paragraph 6 recognized that “WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.” So the TRIPS Council was instructed by the WTO Ministers “to find an expeditious solution to this problem”.

After two years of intense negotiations a WTO General Council Decision of 30 August 2003 was reached that allowed a manufacturer of generic versions of patented products under a compulsory license or government-use provision to export to eligible importing countries, without having to limit the exported amount as originally required in Article 31(f) of the TRIPS Agreement. This Decision constitutes a waiver of the restriction in Article 31(f) and of article 31(h) regarding the remuneration otherwise due in the importing country. The Decision does not limit the range of public health problems that may be addressed under the adopted waivers.

Under the “30 August Decision” as it is commonly called, importing and exporting countries have to take several measures and fulfill several conditions. There are concerns that the required conditions are difficult for the relevant companies and governments to comply with¹²¹. An amendment to the TRIPS Agreement was subsequently agreed upon by the WTO General Council on 6 December 2005, which is essentially the same as the 30 August Decision (this will become Article 31*bis* if two-thirds of WTO Members approve the amendment to enable its entry into force).

Until the required two-thirds of WTO Members officially accept the amendment to bring the amendment into legal force, the 30 August Decision continues to apply. China officially notified the WTO of its acceptance of the Protocol amending the TRIPS Agreement on 28 November 2007.

The first and only Asian country to implement the 30 August Decision in legislation is China. The SIPO Order 37 of 25 November 2005 set out the *Measures to Implement Public Health-related Compulsory Licensing*. When the Patent Law was amended in 2008, Article 50 provided for the implementation of the 30 August Decision: “For the benefit of public health, the patent administration department under the State Council may grant a compulsory license for manufacture of the drug, for which a patent right has been obtained, and for its export to the countries or regions that conform to the provisions of the relevant international treaties to which the People’s Republic of China has acceded.”

E.3.5 Exceptions to patent rights

Article 30 of the TRIPS Agreement allows the use of limited exceptions to patent rights:

“Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and

¹²¹ C Correa, “TRIPS and access to drugs: toward a solution for developing countries without manufacturing capacity?”, *Emory International Review*, vol. 17, No. 2, Summer, 2003.

do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties”.

The scope and nature of these exceptions is not defined so it is up to national law to do so, thus allowing considerable flexibility in accordance with the principles and objectives of the TRIPS Agreement. Exceptions can include provisions to promote research and to protect public health.

An important exception is the ‘Bolar’ (or ‘early working’) exception. This is an exception to patent rights allowing a third party to undertake, without the authorization of the patent holder, acts in respect of a patented product necessary for the purpose of obtaining marketing approval for the sale of a product¹²². This means that a generic medicines manufacturer can take necessary steps during the patent period to get ready and have its product registered by the drug regulatory authority. Then, once the patent period expires, its generic version can rapidly enter the market.

If a country has no manufacturing capacity, a Bolar provision is still useful because it can speed up the registration of a generic product by a foreign supplier so that affordable imports are available.

In China there are currently provisions in the drug registration regulations that allow for registration in anticipation of a patent expiry. Moreover, the Patent Law explicitly provides for the ‘Bolar exception’ in Article 69(5). It is not deemed to be an infringement of a patent right when “Any person produces, uses, or imports patented drugs or patented medical apparatus and instruments, for the purpose of providing information required for administrative examination and approval, or produces or any other person imports patented drugs or patented medical apparatus and instruments especially for that person.”

This is a very positive step for China to reinforce to enable the domestic generic industry to manufacture essential medicines in a timely manner.

E.3.6 Parallel importation

There are significant price differences for patented pharmaceutical products in different markets. A country can legally import the cheapest patented product (without the consent of the patent holder) by applying the principle of ‘international exhaustion’. This means that the first sale by the patent holder or its authorised agent/representative, or by a compulsory licensee, in any country will exhaust the parallel intellectual property right in the importing country. Medicines under a parallel import are usually purchased from a party other than the patent holder (e.g. a wholesaler) who first purchased the medicines from the patent holder or its authorized representative.

The Report of the WHO Commission on Intellectual Property, Innovation and Public Health explains this:

“ ‘Exhaustion’ in intellectual property law essentially means the exact point in the process of sale where the rights of the patent holder become ‘exhausted’. Where the principle of international exhaustion is applied in national law, this is equivalent to allowing what are called parallel imports. In practice, this means a situation, for example, where a wholesaler in Country A makes available to a purchaser in Country B a product patented in both countries at a lower price than it is available in Country B. If Country B allows parallel imports, then the purchaser could import the product at a lower price than the product is available locally. Thus, in principle, parallel imports are a means to reduce the cost of medicines where there are significant inter-country differences in prices” (page 123).

¹²² Report of the WHO Commission on Intellectual Property, Innovation and Public Health (2006), definition in the Glossary.

The TRIPS Agreement (article 6) allows countries to permit parallel importation. However, national laws must explicitly provide for parallel importation. It is advisable to do so by providing for the widest scope, i.e. using the principle of “international exhaustion” for any product legitimately put on the market abroad.

Article 69(1) of China’s Patent Law provides for this flexibility as follows:

“After a patented product or a product directly obtained by using the patented method is sold by the patentee or sold by any unit or individual with the permission of the patentee, any other person uses, offers to sell, sells or imports that product” this shall not be deemed to be an infringement of the patent right.

Thus China is taking a positive step by applying the principle of international exhaustion to allow for parallel imports, i.e. the possibility of importing, for instance, the cheapest priced patented product from anywhere in the world. It would be important to interpret that ‘permission of the patentee’ does not exclude situations where a product has been commercialized under a compulsory license or Government Use.

E.4 Data protection

One very important factor for timely and economical market entry of generic pharmaceutical products is the reliance of the generic manufacturer on the clinical and other test data of the originator company. The market monopoly conferred by a patent for a minimum of 20 years is balanced by generic manufacturers entering the market much later but not having to repeat all the clinical trials and other tests for drugs that are proven to be equivalent. This balance is crucial for promoting access to affordable medicines.

In some jurisdictions test and other data have been subjected to restrictions so that generic manufacturers and drug regulatory authorities are prevented from relying on such data to register generic versions of the drugs for a certain period. The legal regime that is used is called “data exclusivity”.

According to Article 39.3 of the TRIPS Agreement, “Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use”.

Article 39.3 was very controversial in the TRIPS Agreement negotiations, where developing countries explicitly rejected the notion of “data exclusivity” that would prevent drug registration authorities from relying on test and other data from originator companies to register generic versions of the same drug. Generic manufacturers would also be obliged to seek the consent of the originator company to use its data for the registration of the generic product. Moreover, there are strong ethical reasons not to repeat clinical trials once the generic version is proven to be equivalent to the originator drug.

In the marketing approval/drug registration process, the regulatory authority that relies on test data developed by one particular company to approve a generic version is not itself making unfair commercial use of the data. So national drug registration authorities should not be restricted by Article 39.3 and can rely on the data concerned in considering market approval of a generic medicine. These authorities are nevertheless bound to comply with the obligation of non-disclosure.

There are four conditions under Article 39.3 for a party to obtain data protection in the drug marketing approval process:

- The pharmaceutical product utilizes **new chemical entities**;
- The data is **undisclosed**;
- The data was obtained with **considerable effort**;
- The submission of the data is **necessary** to obtain marketing approval.

It is only when these conditions are satisfied that the WTO Member concerned has to meet two obligations under Article 39.3:

- To protect the data submitted for marketing approval against unfair commercial use and
- To protect the submitted data against disclosure by the authorities to third parties. However, disclosure is permitted in two circumstances i.e. to protect the public and to disclose data after taking steps against unfair commercial use.

However, the global pharmaceutical industry, the US government and the EU have consistently demanded developing countries to provide for data exclusivity, especially through bilateral trade or IPR agreements, far beyond the requirements of the TRIPS Agreement.

The Report of the WHO Commission on Intellectual Property, Innovation and Public Health re-affirmed that data exclusivity is not required by TRIPS and is therefore “TRIPS-plus”. It warned about the negative effects that such exclusivity might have in developing countries. While stressing the TRIPS-plus nature of data exclusivity the report noted that “Developing countries need to decide in the light of their own circumstances, what provisions, consistent with the TRIPS agreement, would benefit public health, weighing the positive effects against the negative effects. A public health justification should be required for data protection rules going beyond what is required by the TRIPS agreement. There is unlikely to be such a justification in markets with a limited ability to pay and little innovative capacity. Thus, developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS” (Recommendation 4.20).

The Report stressed that it would be necessary to study the impact on access to medicines that such regulations may have when applied in developing countries¹²³ where, as it is the case for patents, data exclusivity is not likely to encourage any R&D. The opposite result is likely - high prices even in the absence of patent protection.

China agreed to provide data protection for 6 years as a condition to join the WTO. This is contained in Article 35 of the Regulations for Implementation of the Drug Administration Law, applied under the responsibility of the SFDA:

“The State protects undisclosed data of drug study and other data which are independently acquired and submitted by drug manufacturers or sellers to obtain production or marketing approval of the drugs in question which contain new chemical entities. No one may make unfair commercial use of the said data.

123 A number of studies have been made with this purpose. For an analysis of the economic literature on the impact of exclusivity, See Maskus, K. (2006) Literature Survey - Estimating the Price Impact of Reduced Generic Competition. Available at: www.iprsonline.org

Within six years from the date a drug manufacturer or seller obtains the approval documents for producing or marketing a drug containing new chemical entities, if any other applicant uses the data mentioned in the preceding paragraph to apply for approval for production or marketing of the drug in question without permission of the original applicant who has obtained the approval, no approval may be given to any other applicant by the drug regulatory department except that the data submitted are acquired independently.

No drug regulatory department may disclose the data set forth in the first paragraph of this Article except (1) for the need of public interests; or (2) where steps are taken to ensure that the data are protected against unfair commercial use.”

While China agreed to grant 6 years of data exclusivity, the US FTAs with Australia and other countries have a 5-year data exclusivity period. China requires the generic manufacturer to obtain the permission of the originator company to use the data for market approval. But this is highly unlikely as such TRIPS-plus data protection is precisely to prevent competition from the generic sector. Further, the requirement that the generic manufacturers independently develop their own test data is detrimental to the domestic industry and, ultimately, to access to affordable medicines. As noted, there are also ethical issues involved in subjecting patient groups to a second round of clinical trials.

The SFDA regulations were reviewed in 2007 but there was no revision of the provision on data protection.

One option that could be considered by China is to set criteria and conditions for the granting of such data protection, as done by Chile and other countries that also agreed on TRIPS-plus protections in free trade agreements. For instance, protection can be subjected to the filing of the request for marketing approval within a certain period (e.g. one year) from the date of the first marketing approval in the world, and could be terminated in cases of anti-competitive practices or abuses, such as excessive pricing.

F THE ROLE OF CIVIL SOCIETY

The Joint Assessment of HIV/AIDS Prevention, Treatment and Care in China, jointly prepared by the State Council AIDS Working Committee Office and the UN Theme Group on AIDS in China (December 2007) reported the following:

“Many national level mass organizations and civil society groups are actively involved in HIV work and are providing support for the development and capacity building of community-based groups. Provincial STD/AIDS associations have also been strengthened. By the end of October 2007, STD/AIDS associations had been established and further developed in 18 provinces, while many districts and cities had also been motivated to establish STD/AIDS associations.

Civil society organizations and community-based groups are implementing an increasing number of AIDS interventions at various levels. The number of community-based groups, including PLHIV support groups, women’s groups and most-at-risk intervention groups increased from around 100 to over 400 by 2007. More than 6,000 volunteers are working within MSM community groups nationwide at the present time. By participating in project design, implementation and monitoring, the initiatives and commitment of community-based and PLHIV groups continue to be strengthened, which reflects the GIPA principle. Some civil society organizations played an active role in the Global Fund Country Coordinating Mechanism (CCM) reforms. The faith-based organizations, such as Buddhist, Islamic and Christian groups, also participated in the

HIV awareness campaigns and support activities in Xinjiang, Yunnan, Ningxia, Shaanxi, Hunan, Liaoning and other areas".¹²⁴

However, the Joint Assessment also identified challenges:

“Capacity development and engagement: All society involvement is insufficient. Mass organizations involvement is limited, while the capacity and experience of civil society organizations is not satisfactory. Difficulties in obtaining formal registration and legal status have limited the number of community-based organizations working in the AIDS field and constrain the further development and professionalism of these organizations.

Communication channels: There are inadequate communication channels and dialogue between individual civil society organizations, and between civil society, government and other bodies.

Private sector involvement: Involvement in AIDS work by business enterprises and individuals remains limited and the principles and opportunities to incorporate HIV awareness and prevention into the workplace are not widely understood".¹²⁵

The Joint Assessment proceeded to make some recommendations:

“Further adjust and complete regulations and laws to establish an enabling policy environment for the development of civil society organizations dealing with AIDS.

Through different methods, strengthen communication within civil society organizations and between these organizations and related government agencies.

Given the role of civil society organizations in fund-raising, the government also needs to provide support with supplementary financial and technical assistance in accordance with the actual needs. Technical support and guidance should assist civil society organizations to link with target groups that government agencies have difficulty accessing, thereby becoming key partners in the AIDS response, covering both implementation and evaluation of outcomes and impact.

Corporate social responsibility contribution and individual commitment should be fostered, backed by more intensive workplace HIV awareness and anti-discrimination campaigns.

Strengthen the capacity of volunteer groups for more effective involvement in the AIDS response and establish an enabling environment for all society participation."¹²⁶

In a country as geographically extensive and as socially and culturally diverse as China, the potential for social society activism is as promising as it is also challenging. The life and death that characterizes HIV and AIDS, and the hope that treatment can bring as long as there is sustainable and affordable supply of ARVs, have sparked significant self-organizing among the PLHIV community and supporting NGOs. Advocacy NGOs are emerging, and while there are constraints there are also opportunities. The struggle to secure access to treatment and care, of which ARVs availability is a component, has to be one where governments and civil society share the responsibility to search for the best ways to respect human rights.

Since late 2007 the HIV community and the hepatitis B community have explored their common concerns and needs. In tandem with treatment and care support, fighting against discrimination and bringing awareness to the broader society, these communities are also beginning to take on issues related to the legal basis for access to affordable essential drugs.

124 Footnote 2, at pages 14-15.

125 Ibid. at page 35

126 Ibid. at pages 35-36

At the same time, the UN Technical Working Group on Care and Treatment has contributed to civil society inputs in various ways in the period 2006 to 2008. This Working Group co-chaired by the WHO China Office and UNDP, and included among others the UNAIDS, China National Center for AIDS/STD Control and Prevention (a government body), Clinton Foundation, Médecins Sans Frontières, China-MSD HIV/AIDS Partnership, Third World Network, Family Health International, Global Fund Watch Initiative a Chinese NGO.

The goal of the Working Group is to expand access to care, treatment and support for PLHIV in China. Care and treatment issues encompass a wide range of activities ranging from planning care and treatment programs to access to and quality of ARV medicines and diagnostics and monitoring and evaluation.

The main objectives of the Working Group are to:

- Share information, experiences and data;
- Provide in-depth discussions on topics and issues to promote increased understanding and action;
- Increased networking and collaboration.

An area of focus for the Working Group was to tap the intellectual property expertise of members especially from Médecins Sans Frontières and Third World Network, and to share this with the governmental and civil society groups.

The emergence of the China Access to Medicines Research Group in 2007, which brings legal and pharmaceutical expertise, as well as conduct outreach to policy makers, the research community and other NGOs is very encouraging.

As the capacity of domestic civil society groups continues to be built, international NGOs can also respond to opportunities to provide feedback and inputs in legislative revisions and amendments. For example SIPO solicited public feedback to a draft of the proposed revisions to the Patent Law in 2006 and also conducted an on-line session. A call for public feedback is instituted for revision of implementing regulations and measures. Consultations are also conducted from time to time.

SFDA also solicited opinions on its revision of the Provisions for Drug Registration by publicizing a draft for comment on 10 March 2007. A second draft was open for further inputs in June 2007.

The transparency in law making and revision is in large part a response to transparency obligations under China's bilateral and multilateral obligations but it can also be said that a culture of consultation is emerging. The issue is the extent to which the inputs and feedback from consultations (as in other countries or institutions) are taken into account.

Nevertheless in a country where civil society is emerging in various sectors, the HIV community is one of the most vibrant sectors. The potential cooperation between the HIV community and hepatitis B community over a common essential drug – lamivudine (3TC) – is positive as it provides a clearer picture of the scale of need for an essential drug and the obstacles to affordable and sustainable access. Civil society groups have the ability to monitor situations on the ground, alert the government to potential problems (such as shortages of lamivudine in some treatment centres) and be part of the national treatment programme.

G MAIN CONCLUSIONS

There have been impressive achievements in the national response to AIDS. The China country report in the 2012 AIDS Response Country Progress Report (UNAIDS) also reveals the important steps taken over the past five years including the expansion of government-supported ARV schemes. However, the same challenges observed in the Joint Assessment of HIV/AIDS Prevention, Treatment and Care in China, prepared by the State Council AIDS Working Committee Office and the UN Theme Group on AIDS in China in 2007 still remain:

- Programme management and accountability;
- Awareness campaigns and anti-discrimination;
- Comprehensive interventions;
- Treatment, care and support;
- All society involvement;
- Capacity-building of response teams; and
- Monitoring and evaluation systems.¹²⁷

There has been a significant progress in developing a legal framework on intellectual property to address access to pharmaceutical products in China. The National Intellectual Property Strategy adopted by the State Council in June 2008, and the revisions to the Patent Law and the Implementing Regulations have included public health as a focus area. However, there is still a great need for coordination among relevant ministries and agencies to explore options to increase access to affordable pharmaceutical products, including through the grant, where needed, of compulsory licenses and government use of patents.

Further, the recognition that domestic civil society is a part of the solution is an important starting point to forge broader partnerships and improve prevention and treatment of HIV. The United Nations bodies and agencies as well as international NGOs also play a critical role in supporting and facilitating treatment and care. They have also actively contributed to the policy and legal developments in the country.

¹²⁷ See footnote 2.



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