7 PUBLIC HEALTH AND INTELLECTUAL PROPERTY RIGHTS IN THE PROMOTION OF INNOVATION: A MONGOLIAN PERSPECTIVE

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ABSTRACT

This paper aims to address the issues at the interface of public health and intellectual property rights (IPRs) in the Mongolian innovation landscape. It also looks at innovation and entrepreneur initiatives of Mongolian universities and research institutions in solving public health issues in ways responsive to the market economy. At present, the country is paying considerable attention to the intellectual property (IP) potential of national academic institutions as new IP players who promote creativeness and innovation—the necessities of economic competitiveness.

Keywords: *intellectual property, public health, innovation, entrepreneurship, university-industry collaboration, pharmaceutical patents, commercializing intellectual property rights*

'[T]he TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we 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, the Doha Declaration on TRIPS and Public Health.[1]

I. INTRODUCTION

Mongolia has succeeded, within a short period of time, in becoming an active member of the World Trade Organization (WTO)[2] and a signatory to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), as well as treaties adopted by the World Intellectual Property Organization (WIPO). This accession is expected to open opportunities for mutually beneficial and equal-standing trading conditions for Mongolia, leading to economic and social progress. Mongolia belongs to a group of developing countries with limited ability to manufacture the needed amount of lifesaving essential medicines to meet its public health needs; therefore, Mongolia must rely heavily on the importation of the necessary medicines from other countries, creating inherent concerns of high-price effects. In fact, this is a problem that not only affects Mongolia but also impacts many other countries throughout the world, including other WTO Member States.

Mongolia's National Constitution (1992)[3] grants an important civil right of social welfare—health protection and medical services—to its entire population. In addition, the principles of national public-health policy[4] promote quality of human life and better social standards as an essential part of a sustainable social and economic-development programme.[5] Therefore, the provision of affordable medicines and medical services to citizens can be regarded as a priority of the Mongolian Government with maintaining the national public-health system as its chief duty.

Making essential medicines and medical services accessible is an expensive social expenditure and many barriers exist due to the nature of international trade and commerce. However, the increasing integration of global trade, commerce, and bilateral and international trade agreements—with the flexibilities confirmed in TRIPS by the Doha Declaration—have greatly eroded these barriers. In the face of globalization, existing national and international IP regimes, and national innovation—particularly regarding the patent system—are expected to play an important role in creating competitive advantages and valuable assets for innovative pharmaceutical business entities within Mongolia.

In recent years, evolving public-health policy debates that shape the landscape for innovation and access to essential medicine and essential human rights have been hot issues in many international forums. Mongolia is no exception. Innovation may lead to the advancement of medical technology that is vital for survival and enhance the quality and effectiveness of many existing medicines. But innovation also brings about the discussion of stronger patent protection. Moreover, personal

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[1] Doha Declaration on the TRIPS Agreement and Public Health [2001] (WT/MIN(01)/DEC/2).

[2] WTO, Mongolia and the WTO, available online at: <http://www.wto.org/english/thewto_e/countries_e/mongolia_e.htm> accessed 5 May 2013.

[3] Constitution of Mongolia (MGL) 1996, Ch 2, Article 16-6.

[4] National Public Health Policy (MGL) 2001 <http://www.legalinfo.mn/annex/details/3330?lawid=6389> accessed 20 May 2013.

[5] Government of Mongolia (MGL), 'The Action Plan 2012-2016' <http://www.moj.gov.mn/index.php?option=com_content&view=article&id=204%3Aaction-plan&catid=87%3Acontentnews&Itemid=191> accessed 10 October 2013.

aspirations and infrastructural supports for IP culture can be a crucial factor at different social levels for innovative success. Without IPRs, innovative and creative entrepreneurs, including the academic ones, have little incentive to invest in the development of new and innovative medical technologies that could bring the much needed benefits to adopt, adapt and create innovative health products and services.

At present, Mongolia faces increasingly complex questions when managing IPRs in regard to academic entrepreneurship, that is to say, how the public sector collaborates with private companies to utilize knowledge within university walls in order to generate innovation. Indeed, we are facing the prospect of favouring IPRs over human-capital resources. This evolution has already started, and we seek to know where it leads and how the international and national IPR regimes would safely guide the evolution. This paper aims to address the issues at the interface of public health and IPRs in the innovation landscape of Mongolia. It also looks at current innovative and entrepreneurial initiatives of Mongolian universities and research institutions in collaboration with the business sector to solve public-health issues arising from participation in an increasingly global market economy.

II. PUBLIC HEALTH ISSUES IN MONGOLIA

The National Council of Public Health[6], chaired by the Prime Minister of Mongolia, is responsible for formulating national public-health policy to improve the health of Mongolia's population. In addition, the National Public Health Centre (formerly National Public Health Institute) under the Ministry of Health plays an important role in the country's efforts to promote public health and monitor the implementation of national public health policy. The main objective of the current policy is to ensure access to health services for the entire population by targeting and mobilizing the economic, industrial and academic potential of Mongolia. A number of new legislative efforts addressed public health issues in the country, including health insurance, public health infrastructure development and promotion of innovation and research.

The National Health Law (1998) provides the right of equitable access to health services and the Health Insurance Law (1993) denotes the Ministry of Health as the main government institution responsible for establishing requirements relating to benefit packages and tariffs. The Health Sector Development Programme (1988), financially supported by the Asian Development Bank, has played an important role in public health promotion in Mongolia by focusing on public health financial sustainability, infrastructure development, and available potential resources.

The current insufficiently addressed public-health problems include (1) the rising rates of respiratory and cardiovascular chronic diseases; and (2) the widening longevity gap between rich and poor, leading to an unequal access to essential medicines, medical technologies and health care services. Additionally, onlookers are noting the human health effects of a number of environmental factors—including global warming's impact on desert growth and intensive commercial mining started in the mid-to-late 1990s.[7] Environmental issues raised by commercial mining include air and water pollution and the release of potentially hazardous chemicals into human food chains.

Developing universal, plausible public-health initiatives is challenging for Mongolian public health authorities. Policymakers are only now beginning to rectify the low quality care and pervasive inefficiencies in the existing public-health system—an unsustainable situation that exists despite[8] enormous financial resources spent over the years and administrative changes.

Despite the issues outlined above, governmental policies and action remain critical in fostering an environment in which innovation thrives. Accordingly, policymakers should consult and consider the roles of active agents in the public-health realm: health providers, academic and research institutions, customers, and the private medical sector as a whole.[9]

Key here is the fact that the bilateral and multilateral agreements outlined above do not prevent Member States from taking the necessary measures to protect public health and provide access to essential medicines. Therefore, approaches for effectively applying and magnifying IP-related public-health

[6] Ministry of Health, 'Health Situation, Statistical and Policy Report' *(MGL)* (2005) <http://moh.mn/moh%20db/HealthReports.nsf/0/e9e9375a137a3f9dc82571dc0024404f?OpenDocument> accessed 10 September 2013.

[7] WHO Country Cooperation Strategy for Mongolia 2010-2015 <http://www.un-mongolia.mn/publication/CCS_en.pdf> accessed 20 September 2013.

[8] Health Sector Strategic Master Plan (MGL) 2006-2015 <http://moh.mn/moh%20db/healthreports.nsf/32fe9f3e7452a6f3c8256d1b0013e24e/8904815ac1fe3327c8257066000b22eb/$FILE/Health%20Sector%20Strategic%20Master%20Plan%20Volume1.pdf> accessed 11 June 2013.

[9] A Government Regulation on Innovative Medical Technology (2011) (MGL) <http://www.moh.mn/downloads/draft.pdf> accessed 10 September 2013.

measures can be an effective solution for Mongolia in solving its public-health issues.

III. PROMOTION OF INNOVATION IN MONGOLIA

It is generally accepted that creativeness and innovation are necessary factors for social and economic development. Innovation brings new products, new services and new knowledge that improves life and creates new jobs. Therefore, to speed up social change and turn innovative ideas into cost-effective new businesses, Mongolian universities need to be prepared to push innovation forward.

The international IPR regime has a highly dynamic, evolving background. Since IPRs are granted to an inventor by governments as a territorial right, protection and enforcement of IPRs vary significantly among countries. In addition, the territorial nature of IPRs allows for restrictions on the pharmaceutical market in which protection may be offered. The main objective of the TRIPS Agreement is to bring IP issues of international trade and commerce under common international rules and regulations. TRIPS requires at least a minimum level of IPRs, including pharmaceutical patents, from a WTO Member country. Since becoming a signatory to TRIPS, Mongolia has collaborated with the international community, participated in a range of various international, regional and bilateral trade negotiations, and is set to develop a plan to further create, utilize, manage, and protect IPRs.[10] In addition, the accession to TRIPS has led to the harmonization of national IP legislation, including the IPRs mentioned therein[11], and harmonization with the corresponding institutions dealing with IP matters[12] in Mongolia.

As noted above, the TRIPS Agreement and the flexibilities confirmed by the Doha Declaration provide possible solutions for increasing access to essential medicines: compulsory licensing and parallel imports.[13] The Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO General Council in 2003, has created conditions under which Member States may issue compulsory licences to produce and export generic versions of patented medicines to countries with limited or nonexistent pharmaceutical manufacturing capacity.[14] This flexibility is seen in Mongolia's patent law.[15]

Compulsory licensing may offer an option to create access to vital essential medicine in developing countries. For the time being, Mongolia has not issued sufficient compulsory licences to meet the needs of the public health sector. Moreover, numerous commercial dealers of pharmaceutical products from Russia, China, Japan, the European Union, and South Korea compete for the demands of the pharmaceutical market, while providing most necessary medicines to the country. In fact, parallel imports may be a more viable solution in Mongolia for increasing access to essential medicines than compulsory licensing. Theoretically, parallel imports allow pharmaceutical companies to profit by differentiating prices in different markets. In the TRIPS Agreement, parallel importation is justified by the exhaustion of IPRs.[16] Yet, finding a cheap source of essential medicine may also present numerous challenges and concerns.

From a national development-policy perspective, the Health Sector Strategic Master Plan 2002-2015, the Science and Technology Master Plan[17] 2007-2020, and the National Innovation Development Programme 2008-2015 highlight the importance of promoting innovation initiatives in national universities and research institutions.[18] These legal documents underscore the commitment of the Mongolian Government to set up a national innovation system based on encouraging creativeness. Moreover, Mongolian development policies were consolidated by the Law on Science and Technology, introduced in 2006. The Law shows the Mongolian Government's interest in building and

[10] Science and Technology Master Plan of Mongolia (MGL) 2007-2020. Goal 3, Improve the legal and institutional system of protecting and utilizing the results of R&D Strategy and 3.1, Improve the system of protecting and utilizing the intellectual property rights, available online at: <http://www.mecs.gov.mn/data/lavlah/master_paln/science/SCIENCE_MP_eng.pdf> accessed 20 May 2013.

[11] WHO, 'Medicines, WTO and the TRIPS Agreement' <http://www.who.int/medicines/areas/policy/wto_trips/en/index.html> accessed 13 May 2013.

[12] Intellectual Property Office of Mongolia (MGL) <http://ipom.mn/> accessed 13 May 2013; Mongolian National Chamber of Commerce and Industry, Mongolian National Arbitration Centre (MGL) <http://en.mongolchamber.mn/index.php/departments-divisions/126-2011-12-21-114136> accessed 21 May 2013.

[13] Declaration on the TRIPS Agreement and Public Health, available online at: <http://www.wto.org/english/tratop_e/trips_e/ta_docs_e/3_wtmin01dec2_e.pdf> accessed 8 June 2013.

[14] Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, available online at: <http://www.wto.org/english/tratop_e/trips_e/ta_docs_e/3_wtl540_e.pdf >accessed 31 May 2013.

[15] Patent Law (MGL) (2006) Article 20. Compulsory Licence: patent rights can be exploited for the purpose in public interests such as health care. ibid.

[16] Articles 6 of the TRIPS Agreement.

[17] Government of Mongolia, 'Science and Technology Master Plan of Mongolia 2007-2020 (MGL)' <http://unesdoc.unesco.org/images/0015/001514/151490e.pdf>accessed 10 June 2013.

[18] Government of Mongolia, 'Millennium Development Goals-Based Comprehensive National Development Strategy of Mongolia' <http://mofa.gov.mn/coordination/images/stories/resource_docs/nds_approved_eng.pdf> accessed 10 June 2013.

strengthening new business and supporting innovative product strategies.

Additionally, important initiatives were implemented for changes in higher educational curricula aimed at providing students with an understanding of different scientific and technical skills. The goal is for university and industry cooperation to form an entrepreneurial partnership, strengthened by IPRs, that will generate a sustainable rise in productivity and higher economic growth with a strong emphasis on social benefits.

In addition, several laws, including the Patent Law and Copyright Law, are expected to be revised in the near future. The Innovation Law of Mongolia (2012) is Bayh-Dole Act-like. According to the Innovation Law, research findings of government-funded research projects can claim IP protection by inventors or legal entities. With the emergence of a knowledge-based economy and Mongolia's increasing integration into global trade and commerce, an increased understanding of the need to enhance IPRs has arisen. The domestic and international changes require constant improvements to medical products and services in the Mongolian health sector, requiring companies to stay innovative, competitive and confident within IP and the entire framework of law. While it may appear as though Mongolia now has a legal basis for innovation, it is important to realize that the Mongolian Innovation Law is not static, but rather, a living legal document that must be continually evaluated and changed to reflect the needs of society.

IV. ACADEMIC ENTREPRENEURS ARE THE NEW PLAYERS OF INTELLECTUAL PROPERTY RIGHTS

Mongolia has pushed national development policies to improve the quality of higher education in the country, in order to make Mongolia more creative and effective in the light of existing international practices and models. It is well known that, if innovation and entrepreneur initiatives in universities are properly encouraged, both research capabilities and the possibility of great financial returns increase. In this regard, it is important to note, again, that since 2007, the Government of Mongolia has implemented a development-oriented science and technology master plan with long-term policies for national economic development.

National universities and research institutions can be new IP players in Mongolian society. Intellectual property rights are worth little for solving public-health issues in the country, unless they are well-defined and legally enforced in a consistent, certain and predictable manner. Therefore, Mongolia needs a corresponding innovation infrastructure that supports entrepreneurial spirit in the country's national research institutions and universities at a socially optimal level.[19] Innovation is a complex research and development process that entails risks associated with many unpredictable financial and social factors.[20] Therefore, the extent of protection provided to IPRs is related to economic performance and crucial for innovation in national universities, research institutions, and the country's business environment. Equally important, Mongolia needs an active customs service and a consistent court-system response to enforcing IPRs.[21]

V. THE CHALLENGES OF AN 'ENTREPRENEUR UNIVERSITY' IN MONGOLIA

The Mongolian University of Science and Technology (MUST) is one of the best universities in Mongolia with a profound academic and technical background in different fields of engineering science and technology. At the core of MUST and central to our future is a commitment to innovation: to create new, important ideas for the well-being of Mongolian society. MUST is the leading public university in the nation, and its emphasis on teaching, research and service has had a transformative effect on higher education. Recently, a Strategic Roadmap that leads to an 'Entrepreneur University' has been developed to accelerate innovation at MUST.[22]

MUST has declared in its university development policy statement to undertake all the necessary measures to become an 'Entrepreneur University'. In order to achieve this goal, there is a strong need to understand how knowledge-transfer processes and their interaction with IPRs, can be managed to ensure that the university-developed innovations are successfully transferred into the Mongolian economy.

MUST has outlined the following in order to realize the goal of becoming an 'Entrepreneur University':

- Setting up and implementing an appropriate IPR policy to attain university IPRs for purposes of commercializing university-developed IP;

[19] Ministry of Education and Science and Technology, 'Action Plan (MGL)' (2007) <http://www.meds.gov.mn/director-content-140-328.mw> accessed 5 October 2013.
[20] Law on Employee's Invention (MGL) 2012.
[21] Law on Specialized IP and Competition Courts 2012.
[22] Mongolia University of Science and Technology, 'Road Map 2012-2012,' <http://www.must.edu.mn/beta3/modules.php?name=Rectorat&select=result&IDD=157> accessed 10 November 2013.

- establishing and organizing a university IP or technology-transfer office that manages university-developed IP by setting up start-up and spin-off companies and negotiating business deals with related industries and companies; and

- evaluating university-owned intangible assets and attracting investors by the means of fair shareholder structure and profit sharing with university IPR holders.

As with any plan pursued in a dynamic environment, modifications in both objectives and action plans may be necessary to ensure that MUST continues to move toward these goals. To that end, it will be essential to make the MUST-2012 roadmap a dynamic document, reflecting modifications to the trajectory of the university as conditions around and within the university change. After all, the MUST-2012 roadmap is only a tool for advancing the university's mission of engineering higher education service and research. Its ultimate value lies in providing a roadmap for the future that will enable MUST to continue to fulfil its quest for excellence in innovation and higher education.

VI. CONCLUSION

Mongolia faces increasingly complex questions and decisions regarding managing IPRs in such a way so as to promote innovation. At present, Mongolia pays considerable attention to universities and research institutions as new IP players, which can establish an IP and entrepreneur culture in the society. These groups can promote technology transfer by licensing IPRs, investing in IPRs, and taking advantage of these burgeoning sources of innovation.

The TRIPS Agreement does not prevent Member States from protecting public health or promoting access to affordable essential medicines. The TRIPS Agreement and the flexibilities confirmed in TRIPS by the Doha Declaration recognize that technology transfer is also a public-health issue; they both also endorse the use of certain provisions of the Agreement in favour of solving public health issues in Member countries.[23] Mongolia belongs to a group of countries with limited ability to manufacture life-saving essential medicines; these countries must rely heavily on the importation of necessary medicines from other countries with inherent concerns of high-price effects. For the time being, Mongolia has not issued sufficient compulsory licences to meet the needs of its public-health sector. Parallel imports may be considered an effective solution in Mongolia for increasing the access to essential medicines, rather than compulsory licensing.

To meet the actual social and economic needs of Mongolia, university-based entrepreneur promotion should be incorporated into curriculum design. Technology commercialization from universities is a relatively new social responsibility for Mongolian universities, including MUST; however, the growing need is clear and the legal framework is in place to achieve this necessary goal.

[23] *Promoting Access to Medical Technologies and Innovation. Interactions between Public Health, Intellectual Property and Trade*. <http://www.wto.org/english/res_e/booksp_e/pamtiwhowipowto web13_e.pdf> accessed 10 September 2013.