



Faculty of Law

Lund University

**Master of Human Rights and Intellectual  
Property Rights Law**

Master thesis

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**Pharmaceutical Patent in the PR  
China: Adjustment in Public Health  
Concern**

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Field  
Intellectual Property

Autumn 2002

**For my parents, to whom I am  
forever in debt**

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# List of International Instruments

## **Multinational**

Agreement on Trade-Related Aspects of Intellectual Property Rights, signed in Marrakesh, Morocco on 15 April 1994

Convention Establishing the World Intellectual Property Organization, Signed at Stockholm on July 14, 1967 and as amended on September 28, 1979

Convention on the grant of European Patents (European Patent Convention), of 5 October 1973, text as amended by the act revising Article 63 EPC of 17 December 1991 and by decisions of the Administrative Council of the European Patent Organisation of 21 December 1978, 13 December 1994, 20 October 1995, 5 December 1996 and 10 December 1998

Doha Declaration on TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, Adopted on 14 November 2001

Paris Convention for the Protection of Industrial Property, March 20 1883, as last revised at the Stockholm revision Conference, July 14, 1967

Patent Cooperation Treaty, done at Washington on June 19, 1970, amended on October 28, 1979, and modified on February 3, 1984

Vienna Convention on the Law of Treaties, Concluded At Vienna 23 May 1969, Entry Into Force on 27 January 1980, UN Doc A/Conf 39/28, UKTS 58 (1980), 8 ILM 679

## **Bilateral**

Agreement on Trade Relations Between the United States of America and the People's Republic of China of 1979, July 1979, P.R.C.-U.S., U.S.T. 4652

MEMORANDUM OF UNDERSTANDING BETWEEN THE GOVERNMENT OF THE PEOPLE'S REPUBLIC OF CHINA AND THE GOVERNMENT OF THE UNITED STATES OF AMERICA ON THE PROTECTION OF INTELLECTUAL PROPERTY, signed in May 1992

PEOPLE'S REPUBLIC OF CHINA INTELLECTUAL PROPERTY RIGHTS MEMORANDUM OF UNDERSTANDING--1995 ACTION PLAN, signed on 26<sup>th</sup> February 1995

PEOPLE'S REPUBLIC OF CHINA IMPLEMENTATION OF THE 1995  
INTELLECTUAL PROPERTY RIGHTS AGREEMENT—1996, signed on  
16<sup>th</sup> June 1996

# List of Statutes

## China PR

Patent Law of the People's Republic of China, adopted at the 4th Session of the Standing Committee of the Sixth National People's Congress on Mar. 12, 1984

Patent Law of the People's Republic of China, amended by the Decision Regarding the Revision of the Patent Law of the People's Republic of China, adopted at the 27th Session of the Standing Committee of the Seventh National People's Congress on September 4, 1992

Patent Law of the People's Republic of China, amended by the Decision of Decision Regarding the Revision of the Patent Law of the People's Republic of China, adopted at the 17th Session of the Standing Committee of the ninth National People's Congress on August 25th, 2000

Implementing Regulation of the Patent Law, approved by the State Council on 15<sup>th</sup> June, in force on 1<sup>st</sup> July 2001

Guideline for Examination of Patent Application, promulgated by the SPB, revised in accordance with the 2000 Amendment of Patent Law

Rules of Implementing the Regulation on Pharmaceutical Administrative Protection, promulgated by the SPAB on 30<sup>th</sup> December 1992, replaced by a new version promulgated by the SPAB on 24<sup>th</sup> October 2000

Rules of Administrative Review of the Administrative Protection of the Pharmaceuticals, promulgated by the SPAB on 7 July 2000

Law Against Unfair Competition of the People's Republic of China (Unfair Competition Law), promulgated on September 2, 1993, effective December 1, 1993

Copyright Law of People's Republic of China, approved in the 15<sup>th</sup> Session of the 7<sup>th</sup> National Congress on 7<sup>th</sup> September 1990

Implementing Regulation of the Copyright Law, approved by the State Council on 24<sup>th</sup> May 1991

Regulation Protecting Computer Software, promulgated by the State Council on 4<sup>th</sup> June 1991, has been replaced by a new version promulgated by the State Council on 1<sup>st</sup> January 2002

## **United States**

19 U.S.C Sec.2411-2420 (1994)

19 U.S.C Sec. 2101-2495( 1994)

19 U.S.C Sec. 2420(a) (1) (A)-(B)

19 U.S.C Sec. 2242(a) (1) (A)

28 U.S.C. §1498 (1994) (U.S. Executive Order 12889 regarding the implementation of NAFTA)

[35 U.S.C. §101 \(1982\)](#)

[42 U.S.C. §7608 \(2000\)](#) (U.S. Clean Air Act)

42 U.S.C. §2183 (1988)(Atomic Energy Act 1988)

## **Other Countries**

Argentina Patent Law (1995)

Brazilian Patent Law (1986)

Canada Patent Act (1993)

European Directive on Biotechnological Inventions, No. 96/9/EC (Mar. 11, 1996)

Indian Patent Act (1970)

South Africa Medicines and Related Substances Control Amendment Act, No. 90 (1997) (S. Afr.)



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Case 267/95, Merck & Co. v. Primecrown Ltd. (Dec. 1996), European Court of Justice

EU-Canada Generic Pharmaceutical Case, WTO Panel Report on Canada-Patent Protection of Pharmaceutical Products, WT/DS114/R (Mar. 17, 2000)

[Leesona Corp. v. United States, 599 F.2d 958, 969 \(1979\)](#)

South Africa MRSCAA Case

US-India Mailbox Case, First Submission of the United States of America, India-Patent Protection for Pharmaceutical and Agricultural Chemical Products, Mar. 6, 1997; Notification of an Appeal, India-Patent Protection for Pharmaceutical and Agricultural Chemical Products, Oct. 16, 1997, WT/DS50/6 (1997); Report of the Panel, India-Patent Protection for Pharmaceutical and Agricultural Chemical Products, Sept. 5, 1997, WT/DS50/R (1997); WTO Appellate Body Report on India-Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50/AB/R (Dec. 19, 1997); Status Report by India, Addendum, India-Patent Protection for Pharmaceutical and Agricultural Chemical Products, April 15, 1999, WT/DS50/10/Add.4 WT/DS79/6 (1999)

[Walker Process Equipment Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172 \(1965\)](#)

# 1 Introduction

The Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) could be said to be great success of the United States (hereinafter “US”) and other developed countries. Debating over the TRIPS has started since 1994. Debate is especially intensive in TRIPS’ relation with public health concern. TRIPS has set considerably high minimum standards for patent protection, which is objectively in favour of developed countries and multinational pharmaceutical enterprises. On the other hand, developing countries, especially those that are likely to have public health problems, need affordable drugs from different sources, among which competent local pharmaceutical industry is the most reliable source. Thus addressing public health crisis and fostering national pharmaceutical industry are two main and connected challenges most developing countries face when joining the TRIPS.

Both challenges have been reflected not only in the law suits over the new act dealing with HIV/AIDS crisis in the South Africa, the US-India Patent legislation dispute and the Canadian generic pharmaceutical case in the WTO Dispute Settlement Body (DSB), but have also been reflected in debates in international forums such as WTO and WHO.

China started its market economic in the early 1990s. The nascent and non-market oriented national pharmaceutical industry is still in a painful transformation. Because of the incompetence of the health insurance system, the affordability of pharmaceutical products is incredibly low. Similar public health crisis as happened in the South Africa is also very likely to break out in China.

Standing in a public health friendly perspective and bearing fostering national pharmaceutical industry in mind, the paper tries to analyse the international obligations of China and make adjustment to current Chinese patent system.

Part two of the paper presents the history of Chinese patent legislations with focus on interaction with the US foreign trade policy. Part three analyses international obligations of China on intellectual property protection, with focus on the flexibility of TRIPS and the Paris Convention on the Protection of Industrial Property (Paris Convention). In part four, the well-known lawsuit over the South African act dealing with the HIV/AIDS crisis shall be analysed. The 1970 India patent Act, together with India’s struggle with the US, shall be analysed as well. The Fifth part evaluates current Chinese patent legislation in the light of international standards. With the intention to make adjustment in public health concern, patent subject matters, patentability and exceptions to exclusive rights in the Chinese patent system shall be evaluated.

## 2 The Historical Development of the Chinese Patent Legislation

China has experienced the transformation from a communist economy to a socialism market economy. Accordingly, its patent legislation has undergone radical evolution. Since 1978, Chinese patent legislations have also been under constant pressure of US foreign trade policy.

This part of the paper shall first present the legislation history of patent protection in China, witnessing the transformation from communism to a market economy. Secondly, the frequent interaction between the US foreign trade policy and the Chinese patent legislation shall be analysed. Thirdly, the administrative protection system for foreign pharmaceuticals, as a unique specimen of legislation under US pressure and important patent legislation covering the period from 1984 to 1993, shall be analysed in detail.

### 2.1 Development of National Legislations

During the period of Republic of China, the most important patent legislation was the 1944 Patent Law of the Republic of China, however not many patents were granted under this statute.<sup>1</sup> After the establishment of the People's Republic of China, from 1950 to 1978, a series of patent legislations of communism nature had been promulgated. In 1963, the Regulation on Awards for Technical Improvements made all inventions the property of the state and permitted free use of all inventions.<sup>2</sup> In 1978, two years after the death of Chairman Mao, modifications in the regulation allowed actual inventors to receive rewards for their work, although free use of all inventions was still allowed.<sup>3</sup>

China established its State Patent Bureau (hereinafter SPB) in 1980 - two years after amending its patent laws.<sup>4</sup> This effort paved the way for the passage of the Patent Law of the People's Republic of China by the National People's Congress

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<sup>1</sup> See Robert G. Oake, Jr., *A Primer on Chinese Patent Law* (1994) <<http://www.oake.com/primer.htm>>.

<sup>2</sup> See id, at 452

<sup>3</sup> See Ramona L. Taylor, *Tearing Down the Great Wall: China's Road to WTO Accession*, *The Journal of Law and Technology* (2001)

<sup>4</sup> See Ross J. Oehler, Note, *Patent Law in the People's Republic of China: A Primer*, 8 *N.Y.L. Sch. J. Int'l & Comp. L.* 451, 455 (1987).

on March 12, 1984.<sup>5</sup> Coming into force on April 1, 1985, Chinese Patent Law provided protection for a variety of inventions.<sup>6</sup> The law spelled out three requirements for patentability: "Any invention or utility model for which patent rights may be granted must possess novelty, inventiveness and practical applicability."<sup>7</sup> However, the 1984 Patent Law expressly excluded the following categories from patent protection: scientific discoveries; rules and methods for mental activities; methods for the diagnosis or for the treatment of diseases; food, beverages and flavourings; pharmaceutical products and substances obtained by means of chemical process; animal and plant varieties and substances obtained by means of nuclear transformation.<sup>8</sup> The exclusion of pharmaceutical products and substances obtained by means of chemical process meant that certain chemical inventions could not be protected under the 1984 Patent Law.<sup>9</sup> It actually includes, *inter alia*, new pharmaceutical compounds per se,<sup>10</sup> compositions or mixtures of pharmaceutical products<sup>11</sup> and agricultural compounds per se.<sup>12</sup> Patent applications for new uses of known pharmaceutical compounds were treated inconsistently in practice. Some Chinese patent examiners routinely rejected such new use claims,<sup>13</sup> while other Chinese patent examiners would approve them if all requirements for patentability were met.<sup>14</sup>

A patent law existed in China from April 1, 1985 to January 1, 1993, but it provided little protection for pharmaceutical or agricultural products. Other provisions in the 1984 Patent Law (both preceding and following the 1992 revisions) are similar to their US or Europe counterparts. As in the US or Europe, Chinese patent law also grants twenty years monopoly to inventors from the date of filing.<sup>15</sup> A Chinese patent shall be granted to the first person that files a patent application, just like the European system.<sup>16</sup> However, business sectors in the US expressed constant concern over inadequate protection of chemical inventions during the period from 1985 to 1993.

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<sup>5</sup> Patent Law of the People's Republic of China, adopted at the 4th Session of the Standing Committee of the Sixth National People's Congress on Mar. 12, 1984 (hereinafter "1984 Patent Law") See also J. Michael Warner & Han Xiaoqing, The Chinese System of Administrative Protection for Pharmaceuticals, *John Marshall Law Review* (Summer 1998)

<sup>6</sup> See Article 69 the 1984 Patent Law.

<sup>7</sup> See Article 22 of the 1984 Patent Law.

<sup>8</sup> See Article 25 of the 1984 Patent Law, *supra* note 15.

<sup>9</sup> Li Luoying, *Answers to Questions Concerning Patent Protection for Chemical Inventions in China*, *China Pat. & Trademarks*, 23 (April 1989)

<sup>10</sup> *Id.*, at 23

<sup>11</sup> *Id.*, at 23

<sup>12</sup> *Id.*, at 24

<sup>13</sup> *Id.*

<sup>14</sup> See J. Michael Warner & Han Xiaoqing, *supra* note 5

<sup>15</sup> *Id.*, Article 45

<sup>16</sup> *Id.*, Article 9

In 1992, the 1984 Patent Law underwent its first revision under the pressure of the US.<sup>17</sup> Among other changes, Article 25 was modified to allow granting patents to pharmaceutical products and substances obtained by means of chemical process.<sup>18</sup> Because of the 1992 amendment, new pharmaceutical compounds per se, new uses for known pharmaceutical compounds, pharmaceutical compositions, and agricultural compounds per se were eligible for patent protection since January 1, 1993.<sup>19</sup>

Facing the TRIPS, the Standing Committee of the 9<sup>th</sup> People's Congress amended the 1984 Patent Law for the second time on 25<sup>th</sup> August 2000.<sup>20</sup> In the 2000 Amendment, "offering for sale" has been included in the exclusive rights of a patent holder. A third party is prohibited from offering the patented products for sale without the authorization of the patent holder.<sup>21</sup> The 2000 Amendment also explicitly provides that although the invention belongs to the Unit (danwei) when it is invented during the work of the inventor, the inventor must be remunerated.<sup>22</sup> The 2000 Amendment also provides detailed methods of calculating compensation.<sup>23</sup> Furthermore, it admits that the decisions of the SPB may be subjected to judiciary review.<sup>24</sup>

## 2.2 Pressure from the US

The Agreement on Trade Relations Between the United States of America and the People's Republic of China of 1979<sup>25</sup> ("1979 Agreement") marked the beginning of Western intellectual property protection in post-Mao China. Pursuant to this Agreement, China became a member of the World Intellectual Property Organisation ("WIPO Convention") in 1980 and of the Paris Convention for the Protection of Industrial Property in 1984. ("Paris Convention")

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<sup>17</sup> Patent Law of the People's Republic of China, amended by the Decision Regarding the Revision of the Patent Law of the People's Republic of China, adopted at the 27th Session of the Standing Committee of the Seventh National People's Congress on September 4, 1992. (hereinafter, "the 1992 Amendment") In 1996 the Patent Law of the People's Republic of China underwent a second revision, the specifics of which are not relevant to the scope of this paper.

<sup>18</sup> Id, Article 25

<sup>19</sup> Id, Article 69

<sup>20</sup> Patent Law of the People's Republic of China, amended by the Decision of Decision Regarding the Revision of the Patent Law of the People's Republic of China, adopted at the 17th Session of the Standing Committee of the ninth National People's Congress on August 25th, 2000 (hereinafter "the 2000 Amendment")

<sup>21</sup> Id, Article 11

<sup>22</sup> Id, Article 6

<sup>23</sup> Id, Article 60

<sup>24</sup> Id, Article 41

<sup>25</sup> Agreement on Trade Relations Between the United States of America and the People's Republic of China of 1979, July 1979, P.R.C.-U.S., U.S.T. 4652 (hereinafter "the 1979 Agreement")

<sup>26</sup>China also promulgated a new trademark law <sup>27</sup> in 1982 and a new patent Law in 1984.<sup>28</sup>

By the mid-1980s, the United States' attitude had changed. <sup>29</sup> Impatient with the lack of improvement in intellectual property protection in China, the American government started to look for pro-active solutions seeking to solve the Chinese piracy problem. Among the various solutions was Section 301 of the Trade Act of 1974 <sup>30</sup>Aiming to eliminate unfair trade practices and to open foreign markets, <sup>31</sup>Section 301 permits the U.S. President to investigate and impose sanctions on countries engaging in unfair trade practices that threaten the United States' economic interests. <sup>32</sup>

In 1988, Congress introduced the Omnibus Trade and Competitiveness Act, <sup>33</sup> which amended Section 301 by including two new provisions--Super 301 and Special 301. <sup>34</sup> Super 301 required the United States Trade Representative ("USTR") to review U.S. trade expansion priorities and identify priority foreign country practices that pose major barriers to U.S. exports. <sup>35</sup>Special 301 targets only unfair trade practices concerning intellectual property rights. Special 301 requires the USTR to identify foreign countries that provide inadequate intellectual property protection or that deny American intellectual property goods fair or equitable market access. <sup>36</sup> Since the introduction of Super 301 and Special 301, the American government has used these Acts repeatedly to pressure foreign countries to reform their intellectual property legislations. <sup>37</sup>

In 1989, the USTR placed China on the "Priority Watch List." <sup>38</sup> In response to the Priority Watch List designation, China passed a new copyright law <sup>39</sup>and

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<sup>26</sup> Paris Convention for the Protection of Industrial Property, March 20 1883, as last revised at the Stockholm revision Conference, July 14, 1967, <<http://www.wipo.org/treaties/documents/english/word/d-paris.doc>> (hereinafter "the Paris Convention")

<sup>27</sup>Peter K. Yu, From Pirates to Partners: Protecting Intellectual Property in China in the Twenty-First Century, *American University Law Review* 136 (2002)

<sup>28</sup> 1984 Patent Law, *supra* note 5

<sup>29</sup> See Peter K. Yu, *supra* note 27

<sup>30</sup> 19 U.S.C Sec.2411-2420 (1994)

<sup>31</sup> *Id*

<sup>32</sup> *Id*

<sup>33</sup> See 19 U.S.C Sec. 2101-2495( 1994)

<sup>34</sup> Judith Hippler Bello & Alan F. Holmer, *The Heart of the 1988 Trade Act: A Legislative History of the Amendments to Section 301*, in *Aggressive Unilateralism: America's 301 Trade Policy and the World Trading System* 113, 113 (1<sup>st</sup> ed., 1990)

<sup>35</sup> See 19 U.S.C Sec. 2420(a) (1) (A)-(B)

<sup>36</sup> See 19 U.S.C Sec. 2242(a) (1) (A)

<sup>37</sup> Kim Newby, *The Effectiveness of Special 301 in Creating Long Term Copyright Protection for U.S. Companies Overseas*, 21 *Syracuse Journal of International and Comparative Law* 39 (1995)

<sup>38</sup> See Peter K. Yu, *supra* note 27, at 142.

issued new implementing regulations in 1990.<sup>40</sup> A separate set of computer software regulations followed in 1991.<sup>41</sup>

Notwithstanding these legislative efforts, the United States found intellectual property protection in China unsatisfactory. On April 26, 1991, the United States upgraded China to a "Priority Foreign Country."<sup>42</sup> A month later, the United States initiated a Special 301 investigation on China's intellectual property rights practices.<sup>43</sup> Hours before the deadline for imposing sanctions, both countries averted a potential trade war by signing the Memorandum of Understanding Between China (PRC) and the United States on the Protection of Intellectual Property ("1992 MOU").<sup>44</sup>

The 1992 MOU is the most influential agreement on substantial rules protecting pharmaceutical patent in China. Pursuant to the 1992 MOU, China amended the 1984 Patent Law, promulgated new patent Implementing Regulation, and acceded to the Patent Cooperation Treaty.<sup>45</sup> The new patent law extends the duration of patent protection from fifteen to twenty years; affords protection to all chemical inventions, including pharmaceuticals and agricultural chemical products; and sharply restricts the availability of compulsory licenses.<sup>46</sup> The MOU also establishes the pharmaceutical administrative protection system granting exclusive rights to foreign pharmaceutical patents granted during the period from 1984 to 1993.<sup>47</sup>

Though the 1992 MOU was very successful in establishing a modern intellectual property regime in China, American business still complaint about the lack of

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<sup>39</sup> The Copyright Law of People's Republic of China, approved in the 15<sup>th</sup> Session of the 7<sup>th</sup> National Congress on 7<sup>th</sup> September 1990

<[http://www.cnipr.com/copy/coppage/cop\\_zzqfnew.htm](http://www.cnipr.com/copy/coppage/cop_zzqfnew.htm)>

<sup>40</sup> The Implementing Regulation of the Copyright Law, approved by the Sate Council on 24<sup>th</sup> May 1991 <[http://www.cnipr.com/copy/coppage/cop\\_sszx.htm](http://www.cnipr.com/copy/coppage/cop_sszx.htm)>

<sup>41</sup> The Regulation Protecting Computer Software, promulgated by the State Council on 4<sup>th</sup> June 1991, has been replaced by a new version promulgated by the State Council on 1<sup>st</sup> January 2002. <[http://www.cnipr.com/copy/coppage/cop\\_bhtl.htm](http://www.cnipr.com/copy/coppage/cop_bhtl.htm)>

<sup>42</sup> Robert E. Hudec, *Thinking About the New Section 301: Beyond Good and Evil*, in *Aggressive Unilateralism*, supra note 34, at 113.

<sup>43</sup> Id

<sup>44</sup> MEMORANDUM OF UNDERSTANDING BETWEEN THE GOVERNMENT OF THE PEOPLE'S REPUBLIC OF CHINA AND THE GOVERNMENT OF THE UNITED STATES OF AMERICA ON THE PROTECTION OF INTELLECTUAL PROPERTY, signed in May 1992, [http://www.mac.doc.gov/tcc/data/commerce\\_html/tcc\\_2/PRCIntellectual\\_\(3\).html](http://www.mac.doc.gov/tcc/data/commerce_html/tcc_2/PRCIntellectual_(3).html) (hereinafter "the 1992 MOU")

<sup>45</sup> See Peter K. Yu, supra note 27, at 142.

<sup>46</sup> See Article 1, Article 2 of the 1992 MOU, supra note 44; also see Article 25 and Chapter 6 of the 1992 Amendment of Patent Law, supra note 15.

<sup>47</sup> See Article 2 of the 1992 MOU, supra note 44; also see the Regulation on Pharmaceutical Administrative Protection, promulgated by the State Pharmaceutical Administrative Bureau (hereinafter "SPAB") on 19<sup>th</sup> December 1992, in force on 1<sup>st</sup> January 1993, <http://www.yaoxue.net/law/glp/5-007.htm> (hereinafter the Administrative Regulation)

enforcement mechanism in China. On June 30, 1994, the USTR again designated China a Priority Foreign Country and immediately initiated a Special 301 investigation.<sup>48</sup> Despite threats and counter threats, the two countries reached an agreement (“1995 Agreement”),<sup>49</sup> averting another trade war.

The 1995 Agreement is mainly concerned with the issue of enforcement. Initially, many commentators considered the 1995 Agreement “the single most comprehensive and detailed [intellectual property] enforcement agreement the United States had ever concluded.”<sup>50</sup> By November 1995, however, the Agreement had become apparently inadequate to induce effective intellectual property protection in China. On April 30, 1996, the Clinton Administration again designated China as a Priority Foreign Country for its failure to protect intellectual property rights.<sup>51</sup> Both countries threatened to impose sanction on certain categories of goods from the other; a last-minute compromise was reached for the third time.<sup>52</sup> Unlike the 1992 MOU and the 1995 Agreement, which spelled out new terms, the 1996 Accord mainly reaffirmed China’s commitment to protect intellectual property rights. This Accord included measures China had undertaken or would undertake in enforcing intellectual property rights.<sup>53</sup>

Although the US now seems to have moved away from unilateral sanctions and the use of Section 301 investigations, one can hardly predict whether she will return to these coercive tactics if domestic politics generate such a need in the future.<sup>54</sup> Nevertheless, if the American government decided to return to such tactics, it would not be difficult to predict the pattern in which the events would play out in the next confrontation: threatening from US, compromise made between US and China and the lack of enforcement of the compromising agreement. If history has any ability to predict the future, this pattern may very well suggest how the two countries would behave if the United States continued its current self-deluding policy.

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<sup>48</sup> See Robert E Hudec, *supra* note 42, at 114

<sup>49</sup> PEOPLE’S REPUBLIC OF CHINA INTELLECTUAL PROPERTY RIGHTS MEMORANDUM OF UNDERSTANDING--1995 ACTION PLAN, signed on 26<sup>th</sup> February 1995 <<http://www.tcc.mac.doc.gov/cgi-bin/doiit.cgi?204:64:326552087:192>> (hereinafter “the 1995 Agreement”)

<sup>50</sup> See Robert E Hudec, *supra* note 42, at 114

<sup>51</sup> See Robert E Hudec, *supra* note 42, at 115

<sup>52</sup> *Id*

<sup>53</sup> See PEOPLE’S REPUBLIC OF CHINA IMPLEMENTATION OF THE 1995 INTELLECTUAL PROPERTY RIGHTS AGREEMENT—1996, signed on 16<sup>th</sup> June 1996 <<http://www.tcc.mac.doc.gov/cgi-bin/doiit.cgi?204:64:326552087:190>> (hereinafter “the 1996 Accord”)

<sup>54</sup> See Peter K. Yu, *supra* note 27, at 153



Taking close look at these interactions, we may find that the evolution of the Chinese intellectual property protection regime is under constant pressure from the US. China's first modern patent law was promoted by the 1979 Agreement. Specifically, the 1992 MOU forced China to extend its patent subject matters and establish the administrative protection regime protecting foreign pharmaceutical patents granted between 1984 and 1993.

As we shall see in 4.2 of this paper, the 1984 Patent Law is very similar to the Indian 1970 Patent Act, which excluded pharmaceutical products from patentable subject matters. The Indian 1970 Patent Act had been in force before the TRIPS came into for India. However, US forced China to amend the 1984 Patent Law in 1992 to reach the protection level of TRIPS, ten years before TRIPS come into force for China.

High level of patent protection on the paper has already been achieved in China as early as in 1992. However, even under the constant pressure of the 1995 Agreement and the 1996 Accord, implementation of patent legislation is still not satisfactory. To my opinion, the reasons lie in two aspects. First, China is still at the beginning of its transformation stage from an agriculture country to an industrialized country. It has to foster its immature national pharmaceutical industry to meet the enormous demand of domestic market. The 1984 Patent Law, just as the 1970 Indian Patent Act, to a large extent fulfilled its role. The 1992 Amendment was too advanced for the current stage of the development of the national pharmaceutical industry in China at that time. Secondly and in correlation, there is not enough internal motivation for enforcing thigh-level patent protection. The 1992 Amendment benefits foreign patent holders much more than the domestic industry. Two thirds of the invention patents were hold by the foreign companies in 1992, though Chinese people had filed eleven times more applications.<sup>55</sup> Therefore, there would not be enough lobby power from domestic industry to promote implementation and enforcement.

### **2.3 Administrative Protection of Pharmaceutical Patents**

The 1992 Amendment of the 1984 Patent Law extended patent protection to pharmaceuticals and agricultural products. However, during the period between 1984 and 1993, pharmaceuticals were not protected as patents in China. Thus in accordance with the 1992 MOU, the State Council approved the Regulation on Administrative Protection of Pharmaceuticals ("the Administrative Regulations") on December 12, 1992.<sup>56</sup> Eighteen days later the State Pharmaceutical Administration Bureau of the People's Republic of China (SPAB) promulgated the Rules for Implementing the Regulation of Pharmaceutical Administrative

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<sup>55</sup> See Peter K Yu, *supra* note 27 at 206

<sup>56</sup> *Supra* note 47

Protection (“the rules”)<sup>57</sup>. A retrospective administrative protection system protecting foreign pharmaceutical patents was therefore established.

Compared with relevant provisions in the 1992 MOU, the Administrative Regulation provides protection not only to US pharmaceutical patents,<sup>58</sup> but Article 5(2) of the Regulation also grants *foreign patent holders* exclusive marketing rights.<sup>59</sup> Article 3 admits that enterprises, other organizations and individuals from a country or a region that has concluded a bilateral pharmaceutical administrative protection agreement with China are able to apply for administrative protection.<sup>60</sup> Indeed, after the 1992 MOU, China concluded such bilateral agreements to extend administrative protection to pharmaceutical and agriculture chemical products patented in the European Community Countries, Japan and Switzerland.<sup>61</sup>

The exclusive marketing rights granted to foreign patent holders include prohibiting others from making, using or selling the pharmaceutical products in China, however not including offering for sale and importation, which are normally included in the exclusive rights of a patent holder.<sup>62</sup> The protecting period is seven years and six months, starting from the issuing date of the certificate for administrative protection.<sup>63</sup>

The substantial requirements for administrative protection in the Administrative Regulation is the same as in the 1992 MOU. First, the pharmaceuticals must not be subject to protection under the Chinese Patent Law prior to January 1, 1993. If it is already a Chinese patent, the Administrative Regulation is not going to offer overlapping protection. Secondly, the applicant must have already obtained exclusive right to prohibit others from making, using or selling it in the country to which the applicant belongs. The exclusive right must have been obtained between January 1, 1986 and January 1 1993. Thirdly, the pharmaceutical products shall not have already been marketed in China before the filing date of administrative protection.<sup>64</sup>

The substantive requirements are supplemented by a set of documents that the applicant must submit. The documents include: foreign patent certificate; certificate for manufacture or sale in the country that the applicant belongs to; a contract with a competent Chinese enterprise for manufacturing and/or marketing the pharmaceutical products in China. Therefore, foreign pharmaceuticals to be

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<sup>57</sup> The Rules of Implementing the Regulation on Pharmaceutical Administrative Protection, promulgated by the SPAB on 30<sup>th</sup> December 1992, replaced by a new version promulgated by the SPAB on 24<sup>th</sup> October 2000 <<http://www.nxj.gov.cn/news/news003.htm>>

<sup>58</sup> See Article 2 of the 1992 MOU, supra note 44

<sup>59</sup> See Article 5(2) of the Administrative Regulation, supra note 47

<sup>60</sup> Id Article 3

<sup>61</sup> See J. Michel Warner & Han Xiaoqing, supra note 5 at 1177

<sup>62</sup> See Article 19 of the Administrative Regulation, supra note 47

<sup>63</sup> Id Article 13

<sup>64</sup> Id Article 5; See also Article 2 of the 1992 MOU, supra note 44

protected at least have to be marketed or manufactured in China in cooperation with a Chinese enterprise.<sup>65</sup> In this way, foreign pharmaceutical patent holders are prevented from taking advantage of administrative protection for the mere purpose of preventing Chinese domestic industry from producing similar products.

Exclusive right holders may either seek economic compensation in the People's court or request the CAPDP to stop the infringement when infringement happens.<sup>66</sup> Except for the above-mentioned provision, the regulation provides little clue on ways for the award of judicial remedies for infringement. However, the SPAB has published the new Rules of Administrative Review of the Administrative Protection of the Pharmaceuticals ("Rules of Review") on 7 July 2000.<sup>67</sup> The applicants, exclusive right holders or third party may apply for administrative review when a dispute rises<sup>68</sup> Moreover the applicants, exclusive right holders or a third party may appeal to the State Council or claim to certain People's Courts when they do not agree with the result of the review.<sup>69</sup>

The administrative protection system resembles the so-called "mailbox system" provided in article 70. 8 of the TRIPS.<sup>70</sup> The mailbox system keeps the priority date of application and grant exclusive marketing rights to foreign patent holders in countries that may not be implementing the minimum standards of patent protection provided by the TRIPS when it enters into force. The mailbox system restricts its subject matters to pharmaceutical and agricultural chemical products.<sup>71</sup> Similarly, the administrative protection system in China was also trying to supplement the 1984 patent law, in which pharmaceuticals and agricultural chemical products are not protected.

It had to be noted that China became a WTO member in 2001 and the TRIPS shall come into force for China at the end of 2002. However China was forced by the US to amend its patent legislations as early as in 1992 and establish the mailbox system to retrospectively protect foreign patents obtained during 1984 and 1993.

In our view, introducing the "mail-box" system into China at such an early time is harmful to Chinese pharmaceutical industry. First, the administrative protection only grants exclusive marketing rights to *foreign pharmaceutical patent*

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<sup>65</sup> Id Article 8

<sup>66</sup> Id Article 19

<sup>67</sup> Rules of Administrative Review of the Administrative Protection of the Pharmaceuticals, promulgated by the SPAB on 7 July 2000, <[www.newhealth.com.cn/law/law63.htm](http://www.newhealth.com.cn/law/law63.htm)> (hereinafter "Rules of Review")

<sup>68</sup> Id, see Article 4 and Article 5

<sup>69</sup> Id, Article 16

<sup>70</sup> Article 70.8, Agreement on Trade-Related Aspects of Intellectual Property Rights, signed in Marrakesh, Morocco on 15 April 1994

[http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm0\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm) (hereinafter TRIPS)

<sup>71</sup> Id

*holders.* Domestic pharmaceutical inventions invented during 1984-1993 are protected neither by 1984 patent law nor by the administrative protection regime. The “super national treatment” of foreign pharmaceutical patents eliminated all incentives for innovation in the national pharmaceutical industry at that time. Secondly, the administrative protection regime started in 1993 and is still in force to date. Thus expired or almost expired foreign pharmaceutical patents may obtain administrative protection in China only because they are foreign patents that were granted between 1984 and 1993. After 1993, patents are to be granted to pharmaceuticals due to the 1992 Amendment of the Patent Law. However, the administrative protection regime prevents all Chinese inventions that are similar to expired or almost expired foreign patents that has obtained administrative protection in China from enjoying patent protection. In this regard, the far-reaching malicious effect of administrative protection may even impede innovation in Chinese pharmaceutical industry after 1993.

### 3 International Obligations For China

China became a party of the Convention Establishing the World Intellectual Property Organization (WIPO Convention) in 1980.<sup>72</sup> China accessed to the Paris Convention on 19 March 1985<sup>73</sup>, acceded to the Patent Cooperation Convention in 1994<sup>74</sup> and acceded to the Convention on Biological Diversity in 1992. China has become a WTO member in 2001 and the TRIPS shall come into force for China at the end of 2002.

This paper shall focus on *substantive* international obligations that China bears on protecting pharmaceutical patents. There are no substantive provisions in the WIPO Convention. The Patent Cooperation Treaty mainly deals with procedures of international patent application. Thus substantive obligations are mainly provided in the Paris Convention and the TRIPS.

The Paris Convention mainly deals with three substantive issues in patent protection, namely, patentability, the right of priority and compulsory license. Other than national treatment, The Paris Convention has rarely set any minimum standards in patent protection, not to say specific provisions protecting pharmaceutical patents.<sup>75</sup> Right of priority is a procedural issue and thus will not be discussed in this paper.

TRIPS has actually incorporated all substantial provisions concerning patent protection in the Paris Convention.<sup>76</sup> Generally speaking, the provisions in TRIPS (including Paris Convention) concerning objectives and principles, patentability (including subject matters), exclusive rights granted to the patent holders and exceptions to exclusive rights are relevant to pharmaceutical patents. These provisions do not only frequently appear in the different views submitted separately by developing and developed country groups in the forum of WTO, but are also confirmed in the WTO fact sheets on the pharmaceutical patent and

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<sup>72</sup> Convention Establishing the World Intellectual Property Organization, Signed at Stockholm on July 14, 1967 and as amended on September 28, 1979, <<http://www.wipo.int/clea/docs/en/wo/wo029en.htm>> (hereinafter “WIPO Convention”)

<sup>73</sup> Supra note 26

<sup>74</sup> Patent Cooperation Treaty, done at Washington on June 19, 1970, amended on October 28, 1979, and modified on February 3, 1984 <http://www.wipo.int/clea/docs/en/wo/wo021en.htm> (hereinafter PCT)

<sup>75</sup> Frederick Abbot, Thomas Cottier & Francis Gurry, *The International Intellectual Property System: Commentary and Material* 648, 649 (1999)

<sup>76</sup> Article 2 of TRIPS, supra note 70

public health. <sup>77</sup>The Doha Declaration on TRIPS Agreement and Public Health (Doha Declaration) further clarified many of the above-mentioned issues. <sup>78</sup>For the purpose of presentation in this paper, relevant provisions are divided into four groups: (1) objectives and purposes of the TRIPS; (2) subject matters and patentability; (3) compulsory license and (4) parallel importation.

### 3.1 Objectives and Principles

Objectives and principles have their far-reaching effect in the TRIPS. The Doha Declaration confirms that “in applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the objective and purpose of the Agreement as expressed, in particular, in its objectives and principles”. <sup>79</sup>

Reading all the provisions in the light of the objectives and principles is also common practice of the Dispute Settlement Body (DSB) in interpreting the TRIPS. The WTO Appellate Body (AB) articulated principles for interpreting TRIPS in the India - Patented Pharmaceuticals (Mailbox) Case. <sup>80</sup> The AB indicated that the rules of treaty interpretation outlined in Article 31 of the Vienna Convention on the Law of Treaties apply, and that panels and the AB would begin by examining the express terms of the TRIPS, giving them their ordinary meaning in their context, and in light of the *object and purpose* of the agreement. <sup>81</sup> In the Vienna Convention, reference to negotiating history is only used to confirm results derived from analysis of the express text or to aid when express text renders ambiguous meaning. <sup>82</sup>The central point of the AB's decision was that the "legitimate expectations" of Members and private patent holders in Members is not the basis for interpreting the Agreement. <sup>83</sup>What the pharmaceutical sector in the United States and Europe hoped or expected to achieve is not necessary to

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<sup>77</sup> Fact Sheet: TRIPS and Pharmaceutical Patents, April 2001  
[http://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm00\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm) (hereinafter “Fact Sheet”)

<sup>78</sup> Doha Declaration on TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, Adopted on 14 November 2001  
[http://www.wto.org/english/thewto\\_e/mini\\_nist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/mini_nist_e/min01_e/mindecl_trips_e.htm)  
(hereinafter “Doha Declaration”)

<sup>79</sup> Article 5 (a) Doha Declaration, supra note 78

<sup>80</sup> WTO Appellate Body Report on India-Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50/AB/R (Dec. 19, 1997) [hereinafter India - Mailbox Case], <[http://www.wto.org/english/tratop\\_e/dispu\\_e/distab\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/distab_e.htm)>

<sup>81</sup> Id at 45

<sup>82</sup> Article 31 of the Vienna Convention on the Law of Treaties, May 23, 1969, <<http://www.un.org/law/ilc/texts/treaties.htm>>

<sup>83</sup> US-Indian Mailbox Case, supra note 84, at 42

be considered by the treaty interpreter.<sup>84</sup> The meaning of the TRIPS is to be derived from the language agreed upon by the Members.

Though TRIPS confirms that intellectual property rights are private rights,<sup>85</sup> the objectives of the TRIPS are not simply protecting private rights. Moreover, TRIPS states its commitment to "...the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".<sup>86</sup> Bearing the mutual advantage and the social and economic welfare in mind, TRIPS further permits the member states "...in formulating or amending their laws and regulations, to 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".<sup>87</sup> In achieving the balance of rights and obligations, "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 right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology".<sup>88</sup>

The objectives and principles have other corresponding provisions in the TRIPS. These so-called flexibility provisions are crucial in implementing TRIPS in developing countries.<sup>89</sup> Inventions maybe excluded from patentable subject matters on the basis of social and economic welfare consideration.<sup>90</sup> Also, exceptions to exclusive rights of the patent holders are acceptable provided that they are in conformity with other requirements in the TRIPS.<sup>91</sup> Exceptions to exclusive rights may originate from either social and economic welfare consideration or balancing rights and obligation. The principle of addressing abusing of rights most typically reflected in the anti-competition provision, where "nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market".<sup>92</sup>

The Doha Declaration confirms using these flexibility provisions in addressing public health crisis. It reaffirms "the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."<sup>93</sup> It agrees that "TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our

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<sup>84</sup> Id at 48

<sup>85</sup> Preamble of TRIPS, supra note 70

<sup>86</sup> Article 7 of TRIPS, supra note 70

<sup>87</sup> Id Article 8(1)

<sup>88</sup> Id Article 8(2)

<sup>89</sup> Para. 2 Article 4 of the Doha Declaration, supra note 78

<sup>90</sup> Id Article 27(2)

<sup>91</sup> Article 30 and Article 31 of TRIPS, supra note 70

<sup>92</sup> Id Article 40

<sup>93</sup> Supra note 89

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.”

### 3.2 Subject matters and Patentability

When the Uruguay Round of Trade Negotiations for the General Agreement on Tariffs and Trade (GATT) was launched, more than fifty countries, including some developing countries, did not confer patent protection on pharmaceuticals.<sup>94</sup> While some regarded this absence of protection as necessary to promote access to drugs at competitive prices,<sup>95</sup> others criticized it as jeopardizing innovation and unfairly depriving inventors of the benefits generated by their contributions.<sup>96</sup>

Article 27.1 of TRIPS obliges all WTO members to recognize patents in all fields of technology.<sup>97</sup> When in force, the provision shall make direct and permanent excluding pharmaceuticals out of patentable subject matters unacceptable under TRIPS.

On the other hand, two provisions in TRIPS justify excluding pharmaceuticals from patentable subject matters in limited circumstances. The first exception is *ordre public* and other paramount social values, which are the recognized grounds for exceptions from patentability under article 27.2. There is no universally accepted notion of *ordre public*,<sup>98</sup> leaving member countries some

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<sup>94</sup> See UNCTAD, *The TRIPs Agreement and Developing Countries*, New York and Geneva (1996)

<sup>95</sup> The specific implications of the patent system and, particularly, of the introduction of product patents in developing countries in the pharmaceutical field has been extensively discussed Protection (Oldwicks Press 1994); Richard Rozek, *The Consequences of Pharmaceutical Product Patenting: A Critique*, 16 *World Competition--Law & Econs. Rev.* 91 (1993); A. Subramanian, *Trade-Related Intellectual Property Rights and Asian Developing Countries: An Analytical View*, presented at the Conference on Emerging Global Trading Environment and Developing Asia, Manila, Philippines (May 1995); UNCTAD, *supra* note 1.

<sup>96</sup> See Richard Rapp & Richard Rozek, *Benefits and Cost of Intellectual Property Protection in Developing Countries*, 25, No. 5, *J. of World Trade* (1990).

<sup>97</sup> According to article 27.1 of TRIPs, "patents shall be available for any inventions, whether products or processes, in all fields of technology." See Joseph Straus, *Implications of the TRIPs Agreement in the Field of Patent Law*, in *From GATT to TRIPs: The Agreement on Trade-Related Aspects of Intellectual Property Rights*, 18 *IIC Studies* (F.K. Beier & G. Schricker eds., VCH 1996).

<sup>98</sup> For instance, under the Guidelines for Examination of the European Patent Office *ordre public* is linked to security reasons, such as riot or public disorder, and inventions that may lead to criminal or other generally offensive behavior. See *Guidelines for Examination*, Part C,



flexibility to define which situations are covered, depending upon their own social and cultural values. Article 27.2 somehow indicates that the concept is not limited to "security" issues; it also relates to the protection of "human, animal or plant life or health" and may be applied to inventions that may lead to "serious prejudice to the environment." Moreover, Article 27.2 provides that non-patentability on grounds of *ordre public* or other paramount social value are only permissible if necessary to prevent *commercial exploitation* of the invention concerned. In other words, it is not possible to declare the non-patentability of a certain subject matter while permitting at the same time its distribution or sale by any third party.<sup>99</sup>

A second exception that might authorize excluding pharmaceuticals from patentability is article 8.1, which explicitly recognizes the right of WTO members to adopt policies in accordance with public health concerns. However, measures in Article 8.1 appears to be public policy measures, which are out of the regime of intellectual property law. Moreover, the adopted policies are subject to a test of "necessity" and a test of consistency.<sup>100</sup> "Consistency" requires that the policy measures are consistent with other provisions of the TRIPS. Since pharmaceuticals are required to be patentable subject matters in the TRIPS,<sup>101</sup> exclusion of pharmaceuticals from patentable subject matters under Article 8.1 could not be permanent.<sup>102</sup> Exclusions to relieve specific public health emergencies, especially if limited in time, might be justifiable under Article 8.1 if they are a necessary part of an overall strategy for addressing the emergency.

A key consideration we should notice is the *purpose* for which any subject matter exclusion is adopted. If, for example, the same objective could be obtained by imposing permissible compulsory licenses under article 31 of TRIPS, an exclusion of patentability could be viewed as merely an attempt to circumvent the comprehensive procedural preconditions of article 31.<sup>103</sup> However, if local situations are serious enough to justify an *ordre public* exception, then these situations might also justify overriding other articles, such as article 31, in favor of

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ch. IV, 3.1. Traditionally, *ordre public* in U.S. law referred to an invention that was "frivolous or injurious to the well-being, good policy, or sound morals of a society." See Donald S. Chisum & Michael A. Jacobs, *Understanding Intellectual Property Law* 2.5 (1992). In the United States, "the trend is to restrict this subjective public policy approach to utility." *Id.*

<sup>99</sup> See Dan Leskien & Michael Flitner, *Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System*, 6 IPGRI, *Issues in Genetic Resources* (1997).

<sup>100</sup> Article 8(1) of TRIPS, *supra* note 70

<sup>101</sup> See Article 27.1 of TRIPS, *supra* note 70

<sup>102</sup> Carlos M. Correa, *Public Health and Patent Legislation in Developing Countries*, *Tulane Journal of Technology & Intellectual Property* 10 (Spring 2001)

<sup>103</sup> Article 31 of TRIPS, *supra* note 70

some *nonpermanent exclusion* of subject matter under Article 27.2, if that exclusion was necessary to addressing the local situation.<sup>104</sup>

Besides the two exceptions, TRIPS explicitly allows member states exclude certain inventions from patentability, most of which are relevant to pharmaceutical industry: (1) diagnostic, therapeutic and surgical methods; (2) plants and animals other than micro-organisms.<sup>105</sup>

In conclusion, excluding all pharmaceuticals from patentable subject matters is not permitted by the TRIPS. However, in limited circumstances, certain pharmaceuticals may be excluded from patentable subject matters.

### 3.3 Compulsory License

Article 30 of TRIPS allows member states to enact limited compulsory licenses "provided that such [licenses] do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties."<sup>106</sup> The TRIPS drafters neglected to define key terms in Article 30 such as "unreasonably conflicting," "normal exploitation," and "legitimate interests."

Article 31 of TRIPS imposes certain procedural conditions on compulsory license grants. These conditions include: (1) the third party must accept the license on reasonable commercial terms; (2) the license is nonexclusive; (3) the license is non-assignable; (4) the license is authorized predominantly to supply the domestic market; (5) the license is limited to authorized uses; (6) the license may terminate if reason for the grant ceases to exist; (7) adequate remuneration is required and is subject to judicial review; (8) the issuance of a compulsory license is itself subject to judicial review.<sup>107</sup>

Under Article 31, member states may license to work a patent dependant on a prior patent. The dependent patent must "involve an important technical advance of considerable economic significance in relation" to the first patent. The patentee of the first patent is entitled to *cross-license* the second patentee's invention on reasonable terms. Upon licensing the use of the first patent, the second patentee may not assign the right to use the first patent to a third party.<sup>108</sup>

The Doha Declaration has explicitly included public health crisis into the national emergency (or other extreme emergency) that maybe dealt with by the Article 31 (b) of TRIPS.<sup>109</sup> Thus addressing public health crisis could either be a unique

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<sup>104</sup> See Carlos M. Correa, *supra* note 103, at 11

<sup>105</sup> Article 27(3) of TRIPS, *supra* note 70

<sup>106</sup> *Id* Article 30

<sup>107</sup> *Id* Article 31

<sup>108</sup> *Id* Article 31 (I)

<sup>109</sup> *Id* Article 5 (c)

ground of granting compulsory license in Article 8.1 or be included in the ground of emergency in Article 31 (b). In the case of a national emergency or other circumstances of extreme emergency or in case of public non-commercial use, the condition of “reasonable commercial terms” maybe waived, provided that the patent holder shall be informed promptly.<sup>110</sup>

Article 31 of the TRIPS does not limit the number or type of grounds upon which WTO Members may grant compulsory licenses. It states: "Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected . . ." <sup>111</sup>

Moreover, article 40 of the TRIPS allows member states to take measures dealing with anti-competition practices in relation to abusing intellectual property rights. It states that “ nothing in this Agreement shall prevent members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market.” Also, “ a member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices...” Thus compulsory license may be used as effective measures dealing with anti-competition practices of intellectual property holders. Compulsory license on the ground of correcting anti-competition practice need not to be restricted by (b) and (f) of Article 31, namely, the conditions of “reasonable commercial terms” and “predominantly supply the domestic market”.<sup>112</sup>

Article 2.1 of the TRIPS provides: "In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 - 12, and Article 19, of the Paris Convention (1967)." <sup>113</sup> Article 5.A.2 of the Paris Convention provides: "Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work." <sup>114</sup> The condition for compulsory license provided by the Paris Convention is that such measures should be taken to "prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent . . ." <sup>115</sup> This requirement has been interpreted liberally by governments, including

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<sup>110</sup> Id Article 31 (b)

<sup>111</sup> Id

<sup>112</sup> Article 40 of TRIPS, supra note 70

<sup>113</sup> Id Article 2.1

<sup>114</sup> Article 5(a) (2) Paris Convention, supra note 26

<sup>115</sup> Supra note 113

the U.S. government, in authorizing and granting compulsory licenses in a wide variety of contexts.<sup>116</sup>

Moreover, the Paris Convention provides that compulsory license granted on the basis of failure to work or non-sufficient work shall only be granted four years after the application date of the patent or three years after the granting of the patent, whichever date is later.<sup>117</sup>

In the Canada - Patent Protection of Pharmaceutical Products (Generic Pharmaceuticals) report, the WTO panel indicated that WTO Members agree that Article 31 of the TRIPS Agreement is subject to Article 27.1 of the Agreement.<sup>118</sup> This means that compulsory licenses are subject to the requirement that: "patent rights [shall be] enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."<sup>119</sup>

Pharmaceutical producers have argued that Article 27.1 prohibits WTO Members from adopting compulsory licensing legislation that is specifically directed at the pharmaceutical sector and is not generally applicable to other sectors. The panel report in the Canada - Generic Pharmaceuticals Case rejected this line of analysis. Although Article 27.1 of the TRIPS may preclude some forms of differentiation among fields of patented inventions, it certainly does not preclude all differentiation. It prohibits only differentiation that is "discriminatory."<sup>120</sup> The panel in the Canada - Generic Pharmaceuticals Case suggested that the term "discrimination" in TRIPS Article 27.1 should be read flexibly. The panel said: "Article 27 prohibits only discrimination as to the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit *bona fide* exceptions to deal with problems that may exist only in certain product areas."<sup>121</sup> The panel confirms that governments are permitted to adopt different rules for particular product areas, provided that the differences

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<sup>116</sup> Frederick M. Abbott, *II. Discontinuities in the Intellectual Property Regime, The TRIPS-Legality of Measures Taken to Address Public Health Crises: a synopsis*, Widener Law Symposium Journal (Spring 2001)

<sup>117</sup> *Id*

<sup>118</sup> WTO Panel Report on Canada-Patent Protection of Pharmaceutical Products, WT/DS114/R (Mar. 17, 2000), 7.91 [hereinafter Canada - Generic Pharmaceuticals], <[http://www.wto.org/english/tratop\\_e/dispu\\_e/distab\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/distab_e.htm)>

<sup>119</sup> Article 27(1) of TRIPS, *supra* note 70

<sup>120</sup> *Id*

<sup>121</sup> Canada - Generic Pharmaceuticals, *supra* note 18, 7.92.

are adopted for *bona fide* purposes.<sup>122</sup> The panel did not attempt to provide a general rule regarding what differences will be considered *bona fide*.<sup>123</sup>

It is obvious that the factors that will support granting compulsory licenses in the field of pharmaceuticals will not be the same as the factors that support granting compulsory licenses in, for example, the field of machine tools or Internet auctions. Differentiation may be justified. Also the TRIPS expressly provides that Members may adopt necessary measures consistent with other provisions to address public health emergencies.<sup>124</sup> The creation of a system for rapid low-priced access to pharmaceuticals would be a logical and foreseeable mechanism for addressing public health emergencies. In drafting legislation to provide for such access, a government would not be expected to similarly address access to patents for automobile parts, nuclear reactor components and Internet auction software. Different domestic regulatory authorities would be involved. In the pharmaceuticals case, public health authorities are most likely to be involved in reviewing the grounds for granting compulsory license. In other fields of technology, this will not be the case.

In sum, the language of the TRIPS permitting WTO Members to grant compulsory licenses is not ambiguous. The Doha Declaration further confirms that member states have the right to grant compulsory license.<sup>125</sup> The grounds of granting compulsory license are unlimited, though they have to be subjected to the procedural restriction in TRIPS. There is no doubt that a WTO Member facing a public health crisis, and determining that a pharmaceutical product is not available at prices sufficiently low to allow that emergency to be addressed in the public interest, may grant a compulsory license to a party other than the patent holder to produce the drug. According to the opinion of the DSB in the Canada-Generic Pharmaceuticals case, grounds for granting compulsory license on pharmaceutical patents may not be considered as discriminative under TRIPS 27.1 if differentiation in these grounds is for *bona fide* purpose.

### **3.4 Parallel importation**

The TRIPS provides in Article 6: "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4, nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."<sup>126</sup> The express text states that nothing in the TRIPS may be used to address the exhaustion question in *dispute settlement*. Most commentators agree that this formula represents an agreement to disagree among

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<sup>122</sup> Canada - Generic Pharmaceuticals, supra note 18, 7.91.

<sup>123</sup> Id

<sup>124</sup> Article 8 of TRIPS, supra note 70; See also Doha Declaration Article 4 para. 2, supra note 78

<sup>125</sup> Article 5 (b) of Doha Declaration, supra note 78

<sup>126</sup> Id, Article 6

WTO Members on the subject of parallel trade, leaving each Member free to adopt its own policy and rules.<sup>127</sup>

However, Several influential authorities contend that overuse of the exhaustion doctrine would conflict with the exclusive right of importation conferred by article 28(a) of TRIPS and with the restriction of article 27(1) of TRIPS, which forbids discrimination "as to . . . whether products are imported or locally produced."<sup>128</sup> Parallel importation also has the possibility of conflicting with Article 30, which provides that exceptions for exclusive rights should not "unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent holder".

Article 28 of the TRIPS provides: 1. A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing (See footnote 6) for these purposes that product; [Footnote 6: This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.]<sup>129</sup> By its express terms, Article 28 gives patent holders the right to consent to the importation of products into countries where they hold patent rights. This means that patent holders may use their patent rights to prevent infringement by importation. The express language of Article 28 does not address the question of exhaustion, and is specifically cross-referenced to Article 6.

Whether a patent holder in a country must consent to the importation of a potentially infringing product is directly dependent on whether its patent right in that country has previously been exhausted. If in the national legislation, exclusive rights have already been "exhausted" when patented products have been for the first time put in the market of a foreign country, the patent holder no longer has the right to consent to importation. This is what "exhaustion" exactly means, and it is a question that has customarily been reserved to the national law of each state (or to a regional organization). It is a question that Article 28 does not purport to answer.<sup>130</sup> On the other hand, under Article 28 of the TRIPS, patent holders have the right to prevent unauthorized importation of their products that are placed *on the market of the foreign country without their consent*.<sup>131</sup> Article 28 specifically prohibits importing pirated patented products.<sup>132</sup>

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<sup>127</sup> Marco C.E.J. Bronckers, *The Exhaustion of Patent Rights under World Trade Organization Law*, 32 J. World Trade L. 137, 142 (1998)

<sup>128</sup> Article 27.1 of TRIPS, supra note 70; see also Abott, supra note 117

<sup>129</sup> Article 28 of TRIPS, supra note 78

<sup>130</sup> See Frederick M. Abbott, supra note 118, at 78, 79

<sup>131</sup> Article 28 of TRIPS, supra note 70

<sup>132</sup> Id

Article 6 makes it very clear that nothing in the TRIPS shall be used to address exhaustion *in dispute settlement*, including Article 27(1) and Article 30. Even if we remove the context of dispute settlement, parallel importation is not in conflict with Article 27(1) and Article 30. When parallel importation happens, the exclusive rights in the imported products have already been exhausted after the products are put on a foreign market. So, there could not be discrimination in enjoying patent rights, as prohibited by the Article 27 (1), or unreasonable prejudice of the interests of the patent holder, as prohibited by Article 30, since the patent holder no longer holds the exclusive rights to consent to importation.

A number of countries, including the United States, allow the parallel importation of products that are protected by local patents.<sup>133</sup> There is wide consensus among trade and intellectual property experts that the TRIPS allows WTO Members to adopt the exhaustion policy best suited to them at the present time.<sup>134</sup> The Doha Declaration further confirms that the TRIPS intends to “leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.”<sup>135</sup>

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<sup>133</sup> See Margreth Barrett, *The United States' Doctrine of Exhaustion: Parallel importations of Patented Goods*, 27 N. Ky. L. Rev. 911, 918-19 (2000)

<sup>134</sup> Frederick M. Abbott, *Second Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of the Exhaustion of Intellectual Property Rights and Parallel importation*, presented, in London, July 2000, at the 69th Conference of the International Law Association, rev. 1.1

<sup>135</sup> Article 5(d) of Doha Declaration, *supra* note 78

## 4 Models for Comparison: South Africa and India

China has a nascent national pharmaceutical industry. During the years 1996, 1997 and 1998, in the field of chemical pharmaceutical products, there were 3572 foreign patent applications while domestic applications were only 990. In the field of biotechnological pharmaceutical products, there were 886 foreign patent applications while there were only 332 domestic applications.<sup>136</sup> On the other hand, the number of HIV bearers increased 30% from 2000 to 2001, according to the official statistics.<sup>137</sup>

Fostering national pharmaceutical industry and dealing with possible public health crisis are the main concern of developing countries in the debate over TRIPS and public health. These two missions are apparently connected with each other.<sup>138</sup> As we may have concluded from the legislation history analysed above, China has been easily compromised under the pressure of the US and has not adequately considered the demands of the domestic pharmaceutical industry. Also the increasing public health pressure and the insufficient health insurance system urge China to find solutions in domestic patent legislations and administrative law that is out of the intellectual property legal system.

South Africa has provided a very good model in enacting administrative legislation out of the patent legislation regime. It has enacted a new law to allow the ministry of health to grant compulsory license and authorize parallel importation. India, on the other hand, provides a very good example on national patent legislation, especially these legislations concerning subject matters and compulsory license. The 1970 Indian Patent Act sufficiently fosters the development of the national pharmaceutical industry. Moreover, India has struggled hard with the US in the mailbox case and has won priceless time for the development of the domestic pharmaceutical industry.

### 4.1 South Africa

With a population of roughly 26 million people, South Africa is also home of approximately three million reported cases of HIV/AIDS.<sup>139</sup> With 1,500 new

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<sup>136</sup> Wu Hongbo, *The Analysis of Chinese Pharmaceutical Patents Application*, <<http://www.gy-net.com/yiyaozhengce/index0301h.htm>>

<sup>137</sup> April 2002, *Far Eastern Economic Review*

<sup>138</sup> See TRIPS and Public Health, Developing Country's Paper, IP/C/W/296, <[www.WTO.org](http://www.WTO.org)>

<sup>139</sup> AIDS Crisis Predicted for South African Work Force, *Baltimore Sun*, Jan. 28, 1999 at 17A



cases emerging every day, by the year 2005, almost 20% of the workforce is predicted to be infected with the virus.<sup>140</sup>

#### 4.1.1 MRSCAA

In December of 1997 the Prime Minister of South Africa signed the Medicines and Related Substances Control Amendment Act (MRSCAA).<sup>141</sup> The Act addresses South Africa's AIDS pandemic by providing a mechanism through which antiretroviral agents could be made cheaper and more available to South Africa's poor and HIV infected.<sup>142</sup> In particular, the Act contains language granting the South African Minister of Health the power to engage in compulsory licensing and parallel importation of pharmaceuticals. Section 15 (C) (a) provides the Minister of Health with the power to permit the compulsory licensing of pharmaceuticals, so long as the product was initially marketed by the owner or with the owner's consent, but without any other expressed limitation.<sup>143</sup> In addition, section 15 c (b) allows the Minister to permit parallel importation of drugs.<sup>144</sup> It should be noted that the language of the Act is general, allowing the Health Minister to use the Act to increase the availability of any pharmaceuticals used to address any situation, so long as basic criteria are met.<sup>145</sup>

Section 15 (c) (a) and (b) are aimed at increasing local price competition and lowering prices by allowing the importation of drugs from other countries where they are cheaper.<sup>146</sup> It has also been suggested that this section gives South Africa leverage to force the industry to lower their prices.<sup>147</sup> The minister of health can

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<sup>140</sup> Id; see also Matthew Kramer, *The Bolar Amendment Abroad: Preserving the Integrity of American Patent Overseas after the South African Medicine Act*, Dickinson Journal of International Law 565 (Spring 2000)

<sup>141</sup> Medicines and Related Substances Control Amendment Act, No. 90 (1997) (S. Afr.) (hereinafter MRSCAA)

<sup>142</sup> Duane Nash, *South Africa's Medicines and Related Substance Control and Amendment Act of 1997*, Berkeley Technology Law Journal 491 (2000)

<sup>143</sup> Medicines and Related Substances Control Amendment Act, No. 90, § 10(a) (1997) (S. Afr.)

<sup>144</sup> Id

<sup>145</sup> Id

<sup>146</sup> See James Love, *Comments of the Consumer Project on Technology to the Portfolio Committee on Health Parliament* (visited Oct. 14, 1998) <<http://www.cptech.or/pharm/sa/sa-10-97.html>>.

<sup>147</sup> David Benjamin Snyder, *South Africa's Medicines and Related Substance Control and Amendment Act: a Spoonful of Sugar or a Bitter Pill to Swallow?* Dickinson Journal of International Law 186 (1999)

threaten to begin parallel importation of a manufacturer's drugs from other countries if the local prices do not conform to rates abroad.<sup>148</sup>

#### 4.1.2 Debate over the MRSCAA

The Act quickly provoked severe criticism from western governments and pharmaceutical interests, who represent the majority of antiretroviral manufacturers.<sup>149</sup> The USTR, in particular, alleged that the Act potentially violated TRIPS, and threatened sanctions in response to the decreased revenue that the Act would cause American pharmaceutical interests.<sup>150</sup> Moreover, the forty-two members of the Pharmaceutical Manufacturers Association of South Africa, composed significantly of local licensees of western pharmaceutical firms, quickly challenged the Act's legality in Pretoria High Court.<sup>151</sup>

In defending the new law, South African Trade and Industry Minister Alec Erwin stated "the government had taken a policy decision to stop drug companies from using their patents to prevent affordable health care." While this is surely the case, the extent to which the law infringes on patent rights is unclear. Upon closer examination, the law does not appear to give the Minister of Health the absolute power to abrogate patent rights, but instead the law seems to simply give her the power to authorize parallel importation and compulsory license.<sup>152</sup>

The United States and South Africa suggest a truce between the Act's supporters and its critics. Specifically, on September 9, 1999, the Pharmaceutical Manufacturers Association of South Africa announced that it would suspend litigation over the Act as a "goodwill gesture" while the Minister of Health considers legislative amendments that will make compliance with TRIPS unambiguous.<sup>153</sup> In response, the Minister of Health agreed to redraft the Act the

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<sup>148</sup> *Id*

<sup>149</sup> See Duane Nash, *supra* note 152, at 492

<sup>150</sup> The USTR report dated April 30, 1999 included the following: "We call on the Government of South Africa to bring its [intellectual property rights] regime into full compliance with TRIPS before the January 1, 2000 deadline ... and clarify that the powers granted in the Medicines Act are consistent with its international obligations and will not be used to weaken or abrogate patent protection." United States Trade Representative, United States Trade Representative, 1999 Report of the United States Trade Representative < <http://www.ustr.gov/releases/1999/04/99-41.html>>

<sup>151</sup> See Duane Nash, *supra* note 152, at 492

<sup>152</sup> See Jacob Dlamini, Erwin Defends Drugs Law, Suggests WTO Intervention, *Bus. Day (S. Afr.)*, Oct. 22, 1997, at 2.

<sup>153</sup> Neil A. Lewis, U.S. Industry to Drop AIDS Drug Lawsuit Against South Africa, *N.Y. Times*, Sept. 10, 1999, at A3.

following year.<sup>154</sup> Eight days later, the USTR announced that the United States and South Africa had resolved their differences. The United States promised to drop threats of trade sanctions against South Africa.<sup>155</sup> In return, South Africa agreed to enforce the Act's compulsory licensing and parallel importation provisions in compliance with TRIPS.

Since South Africa is a developing country, the TRIPS came into force for South Africa in 2000.<sup>156</sup> As I have already analyzed in the 3.4 of this paper, parallel importation established by the Section 15 (C) (b) is consistent with the TRIPS, especially when the Doha Declaration confirms that each member may be free to adopt its own regime of exhaustion.<sup>157</sup> As for the compulsory license system established under Section 15 (C) (a), though the wording of the provision seems to be so broad that may endanger all exclusive rights held by the pharmaceutical patent holders, the South Africa government finally has agreed to enforce the compulsory licensing in compliance with TRIPS. If Section 15 (C) (a) is subjected to the procedural conditions of Article 31 of the TRIPS and the three-step test in the Article 30, this provision could not be an unreasonable infringement of the exclusive rights of the patent holders.<sup>158</sup> In the developing countries' paper submitted to the discussion on the TRIPS and public health, the practice of South Africa has been viewed as a great success and a good example for domestic legislation dealing with public health crisis.<sup>159</sup>

## 4.2 India

The India 1970 Patent Act explicitly excludes food and medicine from the subject matters of product patent. Also this Act grants the central government the authority to grant compulsory license if the patent holder "could not meet the reasonable requirement of the general public." Though in 1994 India admits that pharmaceutical and food may be patentable, the exclusive marketing rights guaranteed by the "mail-box" system is not to be granted to foreign pharmaceutical patents until 2005.

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<sup>154</sup> Id

<sup>155</sup> A press release from the Office of the USTR, dated September 17, 1999, Office of the United States Trade Representative, U.S.--South Africa Understanding on Intellectual Property (Sept. 17, 1999) <<http://www.ustr.gov/releases/1999/09/99-76.html>>

<sup>156</sup> Article 65.2 of TRIPS, supra note 70

<sup>157</sup> Article 5(d) Doha Declaration, supra note 78; see also the last paragraph of 4.3 of this paper

<sup>158</sup> See the last paragraph of 4.2 of this paper

<sup>159</sup> See the Developing Countries' Paper, supra note 148

The rationale behind this legislation is that most pharmaceutical patents in India are foreign patents. India's use of 1970 Act fosters a strong and profitable domestic generic drug industry, which not only could fulfil the "reasonable" requirements of the general public, but also contributes to its national economic.

India has also been under the pressure from the US. US brought India to the WTO DSB in the well-known "mail box" case because India refused to adopt a "mail-box" system before the substantial amendment of the 1970 Patent Act came into force in accordance with TRIPS. India struggled very hard from 1996 to 1999 even though the AB ruled in favour of the US. The Indian government brought into force special measures equal to the "mail box" system as late as in 1999.

#### **4.2.1 Patentable Subject Matters**

Section 48 (2) of the 1970 Indian Patent Act provides two types of patents: process patents--a patent for a method or process of manufacturing an article or substance whereby the patentee gains the "exclusive right ... to use or exercise the method or process in India"; product patents--a patent for an article or substance whereby the patentee gains the "exclusive right ... to make, use, exercise, sell or distribute such articles or substance in India".

Section 5 provides that, in relation to certain categories of inventions, only process patents are available. Product patents are not available for inventions: (a) claiming substances intended for use, or capable of being used, as food or medicine or drug; or (b) relating to substances prepared or produced by chemical process (including alloys, optical glass, semi conductors and inter-metallic compounds). Medicine and drugs are defined very widely in section 2 (1).<sup>160</sup>

It is therefore not possible to gain product patents in relation to good, medicine and drugs. This has caused the greatest amount of controversy at an international level. By comparison with the level of protection in developed countries, pharmaceutical patents are vastly under protected in India.

#### **4.2.2 Compulsory License, Licensing and Revocation of Rights**

The patentee has a three-year grace period from obtaining of the patent before a compulsory license can be granted. After this any person can apply for a compulsory license where: "the reasonable requirements of the public with

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<sup>160</sup> Id

respect to the patented invention have not been satisfied or [where] the patented invention is not available to the public at a reasonable price..."<sup>161</sup>

The Central government may make an application under section 86 (1) that a patent be endorsed with a license of right. These are also determined according to the "reasonable requirements" criteria. Process patents for inventions relating to food, medicine, drugs or chemical processes are automatically endorsed with licenses of right three years after they are granted.<sup>162</sup> Once an invention has been endorsed with a license of right, any person may request that they be granted a license to exploit it. They need not to show that the patentee has failed to make full use of the patent or is unable to work the invention effectively.

The Central government may apply to the Controller to revoke a patent if it feels that the reasonable requirements of the public have not been met or the invention is not available at a reasonable price. This may occur only after two years have passed from the date a compulsory license or license of right was granted. In determining whether to revoke a patent, whether the patentee has failed to develop the related industry in India is relevant.<sup>163</sup> The Central government may also revoke a patent if "the mode of its exercise is mischievous to the state or generally prejudicial to the public."<sup>164</sup>

Notably, a patent owner may be subject to a license or revocation if it fails to work the invention in India or where demand for the invention is substantially being met by importation. Further, importation does not qualify as working the patent under the Act.<sup>165</sup> This limits the ability of a foreign patent owner to obtain a patent for the mere purpose of preventing importation by competitors or preventing local production. The invention must be worked in India and Indian demand must be substantially met by local production to avoid failing to meet the "reasonable requirements" criteria.

### **4.2.3 Underline Rationale of the 1970 Indian Patent Act**

Essentially, the Patents Act 1970 focuses on the public interest rather than on the protection of private property interests. Its underlying philosophy is expressed in section 83 which states: ... patents are granted to encourage inventions and to ensure that the inventions are worked in India on a commercial scale and to the

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<sup>161</sup> Ahuja, *GATT and TRIPs--The Impact on the Indian Pharmaceutical Industry*, Patent World 28 (September 1994)

<sup>162</sup> Id at 13

<sup>163</sup> McLeland and Toole, *Patent systems in less developed countries: the cases of Indian and the Andean pact countries*, Journal of Law and Technology 235 (1987 2 (2))

<sup>164</sup> See Elizabeth Henderson, supra note 175 at 659

<sup>165</sup> See Ahuja supra note 177 at 29

fullest extent that is reasonably practicable without undue delay ... they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.<sup>166</sup>

From the 1970 Indian patent Act, we find that Indian government grants exclusive rights to exploit an invention on a *quid pro quo* basis. In return for exclusive rights the patent owner works the invention in India leading to the establishment of a new industry, increased employment and capital. The patent owner must also disclose the invention so that the public can work it once the patent has expired. Patent law revolves around this bargain--exclusive rights in exchange for knowledge and input into the local economy. The Patents Act 1970 substantially limits the range of patentable inventions and lists numerous categories of inventions that are not patentable. Although the Act provides certain protection of the rights of patent owners, it also provides the government with substantial powers to restrict those rights.<sup>167</sup>

#### 4.2.4 The US-Indian Mailbox Case

India is a WTO member since 1994. As a developing country, the TRIPS came into force for India in 2000.<sup>168</sup> On December 31, 1994, the President of India promulgated the 1994 Patents Ordinance (1994 Amendment) to amend the 1970 Patents Act of India and increase patent protection.<sup>169</sup> The 1994 Amendment stipulated that applications claiming patent protection for pharmaceutical and agricultural chemical product inventions would be accepted. However, the 1994 Amendment also declared that such accepted patents were not patentable yet, that their handling would be deferred until January 1, 2005 or until an application for the grant of an exclusive marketing right for the patent in question occurred.<sup>170</sup> The 1994 Amendment lapsed on March 26, 1995 when Parliament failed to take the matter up within the deadline.<sup>171</sup> In March of 1995, the Lower House of the Indian Parliament passed a 1995 Patents [Amendment] Bill (1995 Bill) intended to give permanent legislative effect to the provisions of the 1994

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<sup>166</sup> Id

<sup>167</sup> Id

<sup>168</sup> David K. Tomar, *A Look into the WTO Pharmaceutical Patent Dispute Between the United States and India*, Wisconsin International Law Journal (Fall 1999)

<sup>169</sup> See Report of the Panel, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Sept. 5, 1997, WT/DS50/R (1997) at 2.3 [[hereinafter Panel Report].

<sup>170</sup> Id

<sup>171</sup> Id at 2.5

Amendment,<sup>172</sup> however, lapsed in May 1995 because the Upper house refused to pass it.<sup>173</sup>

In response, the Office of the United States Trade Representative (USTR) named India on its list of priority watch countries on May 1, 1996.<sup>174</sup> On July 8, 1996 the USTR opened a formal investigation to review India's alleged failure to provide patent protection for pharmaceutical and agricultural chemical products, as required under the TRIPS Agreement.<sup>175</sup> The United States presented its first submission to a WTO Dispute Settlement Panel (Panel) on March 6, 1997,<sup>176</sup> The United States alleged violations of Articles 70(8) ("mailbox" system) and 70(9) (exclusive marketing rights) of the TRIPS.<sup>177</sup>

On September 5, 1997, the panel concluded that India failed to comply with its obligations under Article 70(8)(a), and, in the alternative, paragraphs 1 and 2 of Article 63 of the TRIPS.<sup>178</sup> India failed to establish a mechanism that adequately preserves novelty and priority for product patents for pharmaceutical and agricultural chemical inventions, as required by Article 70(8) of the TRIPS.<sup>179</sup> Further, the Panel concluded that India did not comply with its obligations under Article 70(9) of the TRIPS in failing to establish a system for the grant of exclusive marketing rights.<sup>180</sup>

On October 16, 1997, India notified the WTO of its decision to appeal the Panel's findings and conclusions.<sup>181</sup> India requested the Appellate Body to review the Panel's findings and conclusions regarding Articles 70(8) and 70(9), as well as Article 63 of the TRIPS Agreement, regarding the transparency of relevant legislations.<sup>182</sup> India's strongest argument centered on Articles 70(9) and 63. Article 70(9) grants exclusive marketing rights to the patentee. In this case, Article

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<sup>172</sup> Id

<sup>173</sup> Id

<sup>174</sup> See [U.S. Opens Investigation into Protection of Intellectual Property Rights in India](#), 13 *Int'l Trade Rep. (BNA)* 28, 1117 (1996).

<sup>175</sup> Id

<sup>176</sup> See First Submission of the United States of America, India-Patent Protection for Pharmaceutical and Agricultural Chemical Products, Mar. 6, 1997 [[hereinafter First Submission].

<sup>177</sup> Id, see also 70.8 and 70.9 of the TRIPS, supra note 70

<sup>178</sup> See Panel Report, supra note 185 at 8.1

<sup>179</sup> Id

<sup>180</sup> Id

<sup>181</sup> See Notification of an Appeal, India-Patent Protection for Pharmaceutical and Agricultural Chemical Products, Oct. 16, 1997, WT/DS50/6 (1997) [hereinafter Notification of Appeal].

<sup>182</sup> See id. at 2(A)-(C).

70(9) required that (1) a "mailbox" application be filed in India; (2) a patent application be filed and approved in another Member country, after January 1, 1995; (3) another Member country approves the marketing of the product; and (4) India approves the marketing of the product.<sup>183</sup> The Panel determined India had not denied the grant of exclusive marketing rights to applicants who had met the above conditions.<sup>184</sup> However, the Panel determined that India did not comply with Article 70(9) due to its' failure to implement any system for the grant of exclusive marketing rights.<sup>185</sup> India responded in their Notification of Appeal that Article 70(9) of the TRIPS Agreement does not require the establishment of such a system.<sup>186</sup>

On December 19, 1997, the Appellate Body issued its report.<sup>187</sup> The Appellate Body upheld the findings and conclusions of the Panel regarding Articles 70(8) and 70(9), but reversed the Panel's conclusion regarding paragraph 1 and 2 of Article 63 of the TRIPS Agreement.<sup>188</sup> While the Article 63 decision was overturned, the bulk of the findings against India were upheld. In August of 1998, a WTO dispute panel reaffirmed that India violated WTO rules by not implementing a "mailbox" system for the reception of patents for pharmaceuticals.<sup>189</sup> The determination of an implementation date was the only issue that remained. While India believed a June 16, 1999 deadline was reasonable, the United States saw no reason for further delay.<sup>190</sup> The parties eventually agreed to a deadline date of April 19, 1999. Another 1998 Amendment was passed by both Houses of the Parliament on March 26, 1999.<sup>191</sup> With this passage, India fully complied with the recommendation of the DSB.<sup>192</sup>

From the US-India mailbox case, we see the benefits of refusing introducing the "mail-box" system. Even after India has been a WTO member in 1995, it has struggled four years in the mailbox case to resist granting exclusive marketing

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<sup>183</sup> See *id.* at art. 70(9).

<sup>184</sup> See Panel Report, *supra* note 185, at 8.1.

<sup>185</sup> *Id.*

<sup>186</sup> See Notification of Appeal, *supra* note 197, at 2(B)

<sup>187</sup> See Report of the Appellate Body, India-Patent Protection for Pharmaceutical and Agricultural Chemical Products, Dec. 19, 1997, WT/DS50/AB/R (1997) [hereinafter Appellate Report].

<sup>188</sup> *Id.* at 97

<sup>189</sup> See WTO: United States, Europeans Win WTO Dispute over South Korean Taxes on Imported Liquor, *Int'l Trade Daily* (BNA), Aug. 4, 1998.

<sup>190</sup> See [Intellectual Property: U.S., India Spar Again on Protection of U.S. Drug, Farm Chemical Patents, 15 Int'l Trade Rep. \(BNA\) 276 \(Feb. 18, 1998\)](#)

<sup>191</sup> Status Report by India, Addendum, India-Patent Protection for Pharmaceutical and Agricultural Chemical Products, April 15, 1999, WT/DS50/10/Add.4 WT/DS79/6 (1999)

<sup>192</sup> *Id.*



rights to foreign pharmaceuticals. The mailbox system came into force in India in February 1999. Four-year struggle is very important to domestic pharmaceutical industry, since domestic industry may patent their similar pharmaceutical products during the time. Therefore, even though the mailbox system was introduced in 1999, similar foreign pharmaceutical patents could not obtain exclusive marketing rights at that time because of the existence of similar domestic patents.

## 5 Re-Evaluation of Current Chinese Patent Legislation

The consistency of the current Chinese patent legislation with TRIPS (including the Paris Convention) shall be evaluated. Suggestions in favor of domestic pharmaceutical industry and better legislative measures dealing with public health crisis shall be proposed. When necessary, Chinese patent legislation shall be compared with the Indian 1970 Patent Act and MRSCAA of South Africa, bearing in mind that the Indian 1970 Patent Act has fostered competent domestic pharmaceutical industry and the South African MRSCAA grants significant power to the ministry of health to deal with the HIV/AIDS crisis.

### 5.1 Patentable Subject Matters

As explained in the 2.1 and 2.2 of this paper, the 1992 Amendment had added pharmaceutical products and agriculture products into the patentable subject matters. Moreover, the administrative protection regime started to protect foreign pharmaceutical patents granted during 1984 and 1993 since 1 January 1993. Thus currently, Chinese patent legislation is consistent with the non-discrimination requirement provided in the Article 27.1 of the TRIPS.<sup>193</sup>

Article 27. 2 of the TRIPS allows member states to exclude certain inventions from patentable subject matters, based on consideration of *ordre public*, morality or environment.<sup>194</sup> Correspondently Chinese patent legislation excludes inventions that are illegal under national legislations, inventions that are in conflict with public morality and inventions that are in conflict with public interests (including inventions that are dangerous to the environment) from patentable subject matters.<sup>195</sup>

Inventions that can be patentable subject matters are infinite. I shall discuss the patentable subject matters from a functional perspective, dividing them into products, substances existing in nature, uses and methods of diagnosis. Claims and disclosure are issues closely relating to subject matters in the process of patent application. Thus both two issues shall be included in this part as well.

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<sup>193</sup> Article 27.1 of the TRIPS, supra note 70

<sup>194</sup> Id Article 27.2

<sup>195</sup> Id; see also part2 chap. 1 Sec 2.1, 2.2 and 2.3 of The Guideline for Examination of Patent Application, promulgated by the SPB, revised in accordance with the 2000 Amendment of Patent Law <http://www.sipo.gov.cn/sipo/zlsc/sczn/default.htm> (hereinafter “the Guideline”)

### 5.1.1 Products

Chinese patent law protects inventions, utility models and industrial designs.<sup>196</sup> The Implementing Regulation of the 1992 Amendment provides that products maybe protected as inventions, utility models or industrial designs.<sup>197</sup> The patentability requirements and the duration of protection are different among the three different protection form. In practice, product patents are the essential part of all patents ever granted.

In the 1984 Patent Law, chemical substances and pharmaceutical products were excluded from patentable subject matters.<sup>198</sup> Similarly, Indian 1970 Patent Act did not protect pharmaceutical products and food as product patent. Only the way of manufacturing or utilizing pharmaceuticals and food may be protected as process patent.<sup>199</sup> Since the 1992 Amendment, pharmaceutical products are patentable in China.<sup>200</sup> In the Administrative protection regime, foreign pharmaceutical product patent holders are granted exclusive marketing rights in China.<sup>201</sup>

In the pharmaceutical field, chemical compounds, the active component of the pharmaceutical products, are patentable as product patents in China. Once the product patent is granted to the pharmaceutical compound, it enjoys so-called “absolute protection”. The patent holder has the exclusive rights of manufacturing, using, selling and importing the patented chemical compound.<sup>202</sup>

Pharmaceutical composition, mixture consisted of active chemical ingredients, carrier and adjuvant, may be patented as product patent in China as well. However the protection scope shall be limited by the use of the composition. Using the composition on disease other than these diseases that have been claimed in the patent is not infringement of the patent. The issue of claim shall be analyzed in 5.1.5.

Excluding all pharmaceuticals from patentable subject matters is not permissible under TRIPS.<sup>203</sup> However, TRIPS will come into force for China at the end of 2002. Unlike India, China grants patents to pharmaceutical products since 1993.

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<sup>196</sup> Article 2 of the 2000 Amendment, supra note 20

<sup>197</sup> Article 2 of the Implementing Regulation of the Patent Law, approved by the State Council on 15<sup>th</sup> June, in force on 1<sup>st</sup> July 2001 <http://www.iplaw.pku.edu.cn/law/5.htm> (hereinafter “Implementing Regulation”)

<sup>198</sup> Article 25 of the 1984 Patent Law, supra note 5

<sup>199</sup> See Elizabeth Henderson, supra note 178 at 658; see also 4.2.2 of this paper

<sup>200</sup> See Article 25 of the 1992 Amendment, supra note 15

<sup>201</sup> See the Administrative Regulation, supra note 47

<sup>202</sup> See the Zhang Qin Kui, Director of the SPB, *Patent Protection of Pharmaceutical Invention in China* [http://www.cnpatent.com/hy2000/2\\_1.htm](http://www.cnpatent.com/hy2000/2_1.htm); See also Part2 Chap.10 3.1 of the Guideline

<sup>203</sup> See last paragraph of 3.2 of this paper

<sup>204</sup>Moreover, foreign pharmaceutical patents granted during 1984 and 1993 are protected under the administrative protection regime. <sup>205</sup> Considering that pharmaceutical products are essential to the public health situation in China and most of the pharmaceutical patents are held by foreigners, it seems we are too easy to compromise with the pressure from the US. <sup>206</sup>

### 5.1.2 Substances Existing in Nature

Some pharmaceutical products are or consist of natural substances. Plants, in particular, are indispensable source of medicines. <sup>207</sup> Animals, especially mice, are always used as experimental tools in pharmaceutical research. TRIPS allow member states to exclude plants and animals from patentable subject matters. However, It obliges member states to protect micro-organisms and plant varieties under either patent system or a *sui generis* system. <sup>208</sup>

National laws vary considerably when deciding whether natural substances are patentable. In US, an isolated or purified form of a natural product, including genes, is patentable. <sup>209</sup> Also, US has granted patents to plants and animals, provided that they are biologically altered in some way. The European Directive on Biotechnological Inventions<sup>210</sup> adopts a similar approach. The Directive, essentially a declaration of long standing law throughout much of Europe, establishes that "biological material" and substances isolated from nature, including new antibiotics and genes, will be considered patentable. <sup>211</sup> On the other hand, European Patent Office (EPO) explicitly excluded *plant and animal varieties* out of the regime of the patentable subject matters. In the case law of EPO, it has defined the "varieties" in a very narrow way, as narrow as generic in the sense of

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<sup>204</sup> See 1992 Amendment of Patent Law, supra note 15

<sup>205</sup> See 2.3 of this paper

<sup>206</sup> See 2.2 of this paper

<sup>207</sup> See John Lambert, Jitendra Srivastava & Noel Vietmeyer, *Medicinal Plants: Rescuing a Global Heritage*, World Bank Technical Paper No.355, at 1 (Washington D.C. 1997).

<sup>208</sup> See Article 27.3 b of TRIPS, supra note 70; see also 3.2 of this paper

<sup>209</sup> See S.R. Bent, D. Schwab, Conlin & D. Jeffrey, *Intellectual Property Rights in Biotechnology Worldwide* 123 (Stockton Press 1991); Philip Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy* 213 (Clarendon Press 1999). However, the extent of patentability of biological materials in the United States has not yet been addressed, by the U.S. Supreme Court.

<sup>210</sup> See No. 96/9/EC (Mar. 11, 1996). "Biological material which is isolated from its natural environment or processed by means of a technical process may be the subject of an invention even if it already occurred in nature."

<sup>211</sup> See Grubb, supra note 44

Biology, so as to grant patent to a kind of genetically altered mouse in the Harvard Onco-Mouse case.<sup>212</sup>

Generally, natural substances are patentable in China, provided that not only its natural existence has been discovered, but also it is isolated from the natural world for the first time, and it must have industrial value.<sup>213</sup> However, situations are different when considering different kind of natural substances.

*Plants and animals varieties* are explicitly excluded from patentable subject matters in China.<sup>214</sup> though the definition of plant variety is far from clear in the international level. Consistent with the TRIPS, China has a *sui genesis* system protecting the plant varieties, though not very efficient.

Plants and animals are different from plant and animal varieties. Chinese patent legislation keeps silent on whether plants and animals are patentable. Therefore, plants and animals may directly be subject to the patentability test. In the practice of the SPB, only cells of plants and animals have ever been granted patents. Other tissues, such as organs of plant and animals as well as plant and animals themselves have never been patented in China.<sup>215</sup>

Genes have been patented in China since 1993, provided that they have distinguishable functions and the functions have been detected. The Guideline has been amended in 2000 to included genes as patentable subject matter.<sup>216</sup> In China, legislators think that as a country that is wealthy in the resources of genes, China had better grant patents to genes.<sup>217</sup>

In practice, the SPO thinks that micro-organisms are neither plant or animals.<sup>218</sup> Thus micro-organisms could not be plant varieties that have been excluded from patentable subject matters. So, Micro-organisms are patentable in China.<sup>219</sup>

Countries with scarce local research capabilities and countries prioritizing medicine affordability and access may prefer limiting the patentability of substances existing in nature.<sup>220</sup> China prefers to prioritize the affordability of medicine. On the other hand, China has great potential in biological research and

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<sup>212</sup> See selected Chapters of the EPO Annual Report 1995, <<http://www.european-patent-office.org/epo/anrep1.htm>>

<sup>213</sup> See Part 2 Chpt. 10 Sec 2 of the Guideline, supra note 210; See also Zhang Qingkui, supra note 217

<sup>214</sup> Article 25 (4) of the 2000 Amendment, supra note 20

<sup>215</sup> Id; see also Zhang Qinkui, supra note 217

<sup>216</sup> See Zhang Qinkui, supra note 217

<sup>217</sup> Id

<sup>218</sup> Part 2 Chpt. 10 Sec. 7.1.2.1 of the Guideline, supra note 210

<sup>219</sup> Id

<sup>220</sup> See Proposal for Review of Article 27.3.b of the TRIPs Agreement, submitted by Kenya on behalf of the African countries, (proposed Aug. 6, 1999).

biological resources. Among natural substances, China grants patent to cells, genes and micro-organisms. Compared with the EPO and the US, China holds more cautious and restricted attitude towards patenting natural substances, yet China has not excluded all natural substances from patentable subject matters. The practice is consistent with the research capacity of China. We suggest that China should proceed cautiously and keep noticing the practice in the US and Europe.

### 5.1.3 Uses

New chemical substances are hardly found. Most pharmaceutical patents are granted to processes of manufacture, formulations, systems of delivery, and new uses of a known product.<sup>221</sup>

When a new therapeutic use is found for a known product, which had no previous pharmaceutical use, it is normally called the “first indication”. In Europe, under article 54(5) of the European Patent Convention, the identification of the first medical indication of a known product may suffice to obtain a product patent for the product.<sup>222</sup> The US, by contrast, has adopted a stricter approach, confining patents on uses of known product to a particular “method-of-use” patent. Such method-of-use patents only protect the method of using the product; however do not protect the product itself.<sup>223</sup>

In some cases, a new use is discovered for a known product that already has existing pharmaceutical use. It is called the “second indication” of a known product. The European Patent Office (EPO) began to grant “method-of-use” patent to the “second indication” since 1984 provided that the “second indication” is claimed in the “Swiss Formula”. The Swiss formula is the “use of X for the manufacture of a medicine to treat Y.”<sup>224</sup>

In China, a known product could not be granted product patent anymore since the product itself has already lost novelty. Thus neither the “first indication” nor the “second indication” of the known product can render a known product to be patented as product again.<sup>225</sup> However, the same as the US patent practice, a “method of use” patent may be granted to the “first indication” or the “second indication” of a known product.

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<sup>221</sup> See N. Zaveri, *Patents for Medicine: Balanced Patent Law--The Need of the Hour*, Indian Drug Manufacturers' Association 71 (1998).

<sup>222</sup> See Grubb, *supra* note 229 at 218

<sup>223</sup> See Robert P. Merges, *Patent Law and Policy: Cases and Materials* 489 (Michie 1992)

<sup>224</sup> See Grubb, *supra* note 229

<sup>225</sup> See Article 22 of the 2000 Amendment *supra* note 20; see also Zhang Qingkui, *supra* note 217

In the practice of SPO, the claim “use x as a certain medicine to treat disease y” is not acceptable since the claim shall be deemed as therapeutic method, which is not patentable in China<sup>226</sup>. The SPO accepts the claim such as “ use x to produce a medicine to treat disease y” or “ the use of x in producing medicine to treat disease y”. The claim accepted by the SPO is exactly the same as the “Swiss Formula” accepted by the EPO.<sup>227</sup>

There is no specific requirement on the use patent, no matter the “first indication” or the “ second indication”, in the TRIPS. It can be argued that developing countries could benefit from the patentability of new uses either because the identification of new uses may be more affordable than the development of new active ingredients, or because new uses could be directed at specific local diseases or maladies. Thus it is right for China to protect the “first indication” and the “second indication” of a known product in a restricted way.

#### **5.1.4 Methods for Treatment and Diagnostics**

Article 27.3(a) of TRIPS allows members to refuse patenting therapeutic method, method for diagnostics and surgical treatment, including their application to animals.<sup>228</sup> Most countries do not grant patents to such methods, due to ethical reasons or to difficulties in actually enforcing those patents. In addition, a method that is applied to the human body or animals is not considered industrially applicable. If patents are granted to diagnostic or therapeutic methods, they may negatively affect low-income patients' access to required treatments.<sup>229</sup>

“Methods for treatment and diagnostic” are excluded from patentable subject matters in China as well.<sup>230</sup> The method of diagnosis is defined as “the process of discerning, studying and determining sickness within the human body or animal body”.<sup>231</sup> The method of treatment is defined as “ the process of blocking, relieving or eliminating the illness of living human being or animals for the purpose of restoring health or relieving pain”.<sup>232</sup> Method of treatment includes surgical method, medicine treatment, physiological treatment and method of immunization etc.<sup>233</sup>

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<sup>226</sup> See Article 25 of the 2000 Amendment supra note 20

<sup>227</sup> See Part 2 Chpt. 10 Sec. 3.5.2 and Part 2 Chpt. 1 Sec 3.3 of the Guideline supra note 210

<sup>228</sup> Article 27.3 of TRIPS, supra note 70

<sup>229</sup> See Correa, supra note

<sup>230</sup> Article 25(3) of the 2000 Amendment, supra note 20

<sup>231</sup> Id Part 2 chpt. 2 Sec. 3.3.3.1

<sup>232</sup> Id part 2 chpt. 2 Sec. 3.3.2

<sup>233</sup> Id

In China, there are mainly two considerations behind the exclusion: one is the consideration of humanitarian and public morality. It is considered to be the freedom of the doctors to make use of all methods for treatment and diagnostic in saving lives of human beings. Another consideration is the lacking of industrial applicability. These methods are directed at human or animal body so that could not attain industrial applicability in China.<sup>234</sup>

The practice in China is fully consistent with the TRIPS requirement and similar to the common practice among countries.

### 5.1.5 Claims

Patent claims essentially consist of a one-sentence definition of the invention where the technical contribution made by the inventor should be unambiguously spelled out. The scope of patent protection (the exclusive rights of the inventor) and, therefore, the room left for independent research and competition of the third party, is determined by the wording used in claims.

Some countries accept, under certain conditions, *functional claims* whereby the invention is described in terms of what it does rather than what it is. Such claims can allow extremely broad coverage, since they confer exclusive rights on any methods that is appropriate to achieve the claimed functions, i.e., all ways of solving a problem are protected. Functional claims have generally been admitted in the US, though broad functional language that may impede further research, and development has been condemned.<sup>235</sup> The EPO on the other hand, accepts functional claims only when there is no other means to describe the invention in a more precise manner.

Another form of claims is the so-called *product-by-process claim*,<sup>236</sup> where a product is characterized by the process by which it is obtained and not by its elements or structure. These claims are in particular relevant to biological products that cannot be described in terms of their structure, for instance, where a macromolecule is secreted by a micro-organism. "Product-by-process" claims are generally admitted by the EPO and some European countries only if it is

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<sup>234</sup> Part 2 chpt.1 Sec 3.3 of the Guideline, supra note 210

<sup>235</sup> See Mary Helen Sears & Thomas Hahn, *Drafting and Interpreting Means (or Step) Plus Function Patent Claims*, Pat. Y.B. 70 (1999)

<sup>236</sup> These claims may read, for instance, "compounds X when prepared by a process as Y." In the United States, the concept of "means-plus-function" claims is used to describe claims in which the invention is expressed as a means or step for performing a specified function without the recital of structure, material or acts in support thereof.



impossible to define a product by its structural features,<sup>237</sup> and if the product obtained is new and inventive. Under "product-by-process" claims, protection is generally only extended to a product obtained with the claimed process; hence, if the same product were obtained by another process, it would not infringe the existing "product-by-process" claim.<sup>238</sup>

*Use-bound claims* protect the use rather than the product. An infringement of a use-bound claim can only occur when a product is prepared or sold for the specific use claimed in the patent.

In China, claims are divided into two groups: the claim for product and the claim for method. Claim for product includes the claim for rights in products, substances, instruments, tools or other things. It had better be described by composition or structural terms of the product. The claim for method includes claim for rights in method of production, method of use or method of communication, disposal and all other methods. Claim for method may be described by process or procedure.<sup>239</sup>

Functional description of a claim for product is prohibited unless there is no other way to describe the product or the functional description is the clearest way to describe the product. Overtly broad protection in the functional claim than what has been described in the explanation<sup>240</sup> shall be prevented. For instance, if there is only one way of fulfilling particular function has been described in the explanation, other unknown methods fulfilling the same function shall *not* be protected under this functional claim.<sup>241</sup> *Purely* function claim for a product, accepted in the US patent practice, is not allowed in China.

The so-called "use-bound" claim is actually one patentable subject matter in China. Use-bound claim can be eligible as use patent in China, provided the claim is written in correct form. This point has been explained in 5.1.3 of this paper.

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<sup>237</sup> See the decision of the Board of Appeals of the European Patent Office T0150/82 (Feb. 7, 1984).

<sup>238</sup> This limitation in the scope of protection may be overcome if it is interpreted that any product obtainable with the process is protected, a solution that, however, has been refused by many patent offices. See Grubb, *supra* note 229, at 203.

<sup>239</sup> Part 2 Chpt. 2 Sec. 3.1.1 of the Guideline, *supra* note 210

<sup>240</sup> Explanation is a document disclosing all technical characteristics of the invention, see the Guideline Part2 chpt2

<sup>241</sup> *Id* Part 2 chpt. 2 Sec. 3.2.2

In the pharmaceutical field, Chemical compounds, as products, shall be claimed by its name and structure.<sup>242</sup> Chemical composition shall be claimed by its structure. Moreover, Claims for chemical compositions used in pharmaceutical field need to be restricted by its use.<sup>243</sup> Pharmaceutical composition is deemed as use invention of certain chemical compound in China. Therefore, the protecting scope for pharmaceutical composition shall be limited by its use.<sup>244</sup> Only when the chemical compounds or composition cannot be defined or cannot be clearly defined by its name and structure, they may be defined by its method of producing (so-called product-by process claim), provided the new method of production renders the concerning compound new characteristics or new effect.<sup>245</sup>

Micro-organism, if it is patentable subject matter, shall be claimed by both its Latin and Chinese name as well as its place of deposition.<sup>246</sup> Genes shall be claimed by its sequence, or method of producing when the sequence of the gene is not available.<sup>247</sup>

A claim is particularly relevant to health-related inventions, due to the prevailing practices of patenting in this area. Recently, scholars have warned that overly broad patents in the field of biotechnology could remove important research tools from the public domain and block the whole area from further research.<sup>248</sup> The broad protection sometimes conferred in the case of inventions related to pharmaceuticals has also been questioned.<sup>249</sup> Acceptance of broad coverage claims expands the domain under the control of patent owners. Broad claims may have a negative impact on research and could unduly block competition. They are also likely to lead to a great number of legal conflicts, ultimately increasing the costs for companies and consumers.

TRIPS keeps silent on claims. Narrowing the scope of patents through strict claim description and coverage requirements creates more room for innovation and competition. China does well in this aspect. Functional claim is not permitted, pharmaceutical compositions should be restricted by its use and all claims should be consistent with what has been disclosed in the explanation. Giving these

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<sup>242</sup> Id part 2 chpt. 10 Sec. 3.1

<sup>243</sup> Id part 2 chpt. 10 Sec. 3.2

<sup>244</sup> See Zhang Qinkui, *supra* note 208

<sup>245</sup> Id, Part 2 chpt. 10. Sec. 3.3

<sup>246</sup> Id, part 2 chpt. 10. Sec. 7.4.1

<sup>247</sup> Id, part 2 chpt .10 Sec. 7.4.3

<sup>248</sup> See Alan White, *Problems of Patent for Research Tools*, BSLR (Mar. 1998)

<sup>249</sup> B. Keayla, *TRIPs--Impact on Health and Pharmaceuticals, Regional Consultation on WTO Multilateral Trade Agreements and Their Implications on Health-TRIPs* (Bangkok, Aug. 16-18, 1999)

restrictions, overtly broad claim in the pharmaceutical field is not likely to be accepted in China.

### 5.1.6 Disclosure

Patents grant temporary monopolies to inventors in exchange for public disclosure of the invention. The full disclosure of the invention is a basic principle of patent law. Access to the information of the invention is one of the traditional justifications for granting exclusive rights to the inventor.

Moreover, disclosure is directly related to the scope of claims. Normally claims shall not be broader than what has been disclosed in the application documents.<sup>250</sup> The practice is the same in China.<sup>251</sup>

In order to perform its informative function, disclosure should ensure that the invention be understood and be executed by an expert with average skills in the same technological field.<sup>252</sup> In China, disclosure has to be understood by the average skilled person.<sup>253</sup> In the pharmaceutical field, chemical compound and chemical composition shall be disclosed by their name and structure to the extent that the average skilled person may obtain the substance.<sup>254</sup> For chemical composition, besides disclosing its name and structure, proportion of different ingredients in the composition shall also be disclosed.<sup>255</sup>

In China, more importantly, the disclosure is required to teach the average skilled person in the same technological field to carry out the invention and solve the targeted technological problems.<sup>256</sup> In the pharmaceutical field, At least one method of reproduction and one method of use shall be disclosed for both chemical compound and composition. Even for the new chemical compound, at least one way of use shall be provided.<sup>257</sup> Moreover, for chemical compounds and compositions that are used for medicine, their effect and method of use shall be disclosed to a certain extent to enable the average skilled person to use the invention on patients.<sup>258</sup>

Article 29 of TRIPS deals with disclosure. According to the article, members may require the applicant to indicate the best mode for carrying out the invention

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<sup>250</sup> Id

<sup>251</sup> See Article 26.3 of the 2000 Amendment supra note 20; see also part 2 chpt. 2 Sec.2.2 of the Guideline supra note 210

<sup>252</sup> See Carlos M Correa, supra note 103 at 33

<sup>253</sup> See part 2 chpt. 2 Sec. 2.1.1 of the Guideline supra note 210

<sup>254</sup> See part 2 chpt. 10 Sec. 3 of the Guideline, supra note 210

<sup>255</sup> See id part 2 chpt. 10 Sec. 3.2

<sup>256</sup> Id part 2 chpt. 2 Sec. 2.1.3

<sup>257</sup> Id

<sup>258</sup> Id part 2 chpt. 10 sec. 4.1; see also Article 26. 3 of the 2000 Amendment, supra note 20

known to the inventor at the filing or at the priority date of the application. This standard only requires the applicant to submit the best information known at the date of the application or priority. Information available at that time rarely includes the actual expertise for executing the invention, since production has seldom started at that time.<sup>259</sup> The practice in China further requires that methods of carrying out the invention should be fully disclosed. In the pharmaceutical field, the disclosure requirement is even higher. The disclosure requirement in China is high enough to ensure carrying out the invention. Moreover, a high disclosure requirement can eliminate the vagueness in claims and prevent protecting overly broad claims.<sup>260</sup>

## 5.2 Patentability

To apply a patent, an inventor must show that the invention is novel, manifests an "inventive step" (that the invention was non-obvious) and is industrially applicable. The manner in which these criteria are defined and applied is crucial to determine the pool of knowledge that is subtracted from the public domain.<sup>261</sup>

Patentability is acutely important for pharmaceuticals. The registration of a large number of patents on pharmaceutical compositions, therapeutic uses, polymorphs, processes, and forms of administration relating to an active ingredient often permit companies to create a high barrier against competition. If aggressively enforced through "strategic,"<sup>262</sup> or even "sham" litigation practices,<sup>263</sup> multinationals can discourage competition by local companies. Additionally, secondary patents may extend the market power conferred by the original patent.<sup>264</sup> Such abuses may be particularly severe in developing countries where there is a lack or limited tradition in controlling such practices under antitrust regulations.

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<sup>259</sup> See Article 29 of TRIPS, supra note 70, see also Correa, supra note 103

<sup>260</sup> See 5.1.5 of this paper

<sup>261</sup> See Correa, supra note 103

<sup>262</sup> See John Barton, *Adapting the Intellectual Property System to New Technologies*, 10 Int'l J. Tech. Mag. (1995).

<sup>263</sup> The doctrine on "sham" litigation applies when a lawsuit is baseless and there is an intent to use it as a tool for monopolization. See Federal Trade Commission Staff, 1 Anticipating the 21st Century: Competition Policy in the New High-Tech, Global Marketplace (1996).

<sup>264</sup> See [Walker Process Equipment Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172 \(1965\)](#), and subsequent case law on antitrust liability when there is an attempt to enforce invalid patents. See also Arun Chandra, Antitrust Liability for Enforcing a Fraudulent Patent in the United States, Pat. World (Apr. 1999).

It is hard to undo overly broad patents and secondary patents. Once a patent has been granted, it is presumed valid. Challenging parties bear the burden of proving that the patent was wrongly issued. Consumers and small pharmaceutical companies, especially in developing countries, rarely have the resources to challenge overly broad patents, though they bear the cost in higher product prices, and decreased access to patented goods.<sup>265</sup>

The flexibility in applying patentability criteria may vary from country to country and over time. The correct interpretation and application of patentability are crucial for balancing public and private interests. The eligibility standards for novelty and inventive step determine the extent to which free competition prevails.<sup>266</sup>

Less technologically advanced countries may prefer to set higher standards of novelty and inventive step in order to preserve and enhance competition without violating minimum international standards. In doing so, they would simply follow the footsteps of many of today's advanced countries, which adopted similar policies when they were themselves developing countries.<sup>267</sup>

Developing countries should notice that high standards of novelty and inventive step can also work against local innovators who cannot meet these standards. One way to address the problem is to adopt a *sui generis* system that deals with "minor" inventions that fail to meet the patent standard of novelty or inventive step. European countries include *sui generis* industrial design laws that protect appearance designs, and utility model laws that protect "minor" inventions generally.<sup>268</sup> They could be good models.

### 5.2.1 Novelty

The patent system was conceived to reward inventors for contributions to the pool of existing knowledge. The criteria used to define what is new are crucial to the scope of possible limitations to the free access and use of technical knowledge in the public domain. The test of novelty considers how much distance separates one claimed invention from prior art. It applies before the test of inventive step.<sup>269</sup>

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<sup>265</sup> See Grubb, *supra* note 229

<sup>266</sup> see Rick Feinberg, *Peculiar Patents: A Collection on Unusual and Interesting Inventions from the Files of the U.S. Patent Office* (Carol Publ'g Group 1994)

<sup>267</sup> See Robert M. Hunt, *Nonobviousness and the Incentive to Innovate: An Economic Analysis of Intellectual Property Reform*, Federal Reserve Bank of Philadelphia, Working Paper No. 99-3 (1999).

<sup>268</sup> See Carlos M Correa, *supra* note 103 at 23

<sup>269</sup> In China, the novelty test applies before the inventive step test as well. See the Guideline Part 2 chapt 3 sec 1

The novelty requirement in modern patent laws is based on an assessment of the prior art on a universal basis, that is, the prior art anywhere in the world. Generally, novelty is destroyed by previous written publication, prior use, or any other form of public communication.

In China, novelty means the difference from all prior art before the filing date. Prior art in China includes all information in publications, prior use and information communicated to the public through other ways (mainly oral ways) before the filing date.<sup>270</sup> The geographic scope of the “prior art” is different. Publication all over the world is prior art.<sup>271</sup> Prior use includes manufacturing, utilizing, selling, importing or modelling the claimed invention *within China*.<sup>272</sup> Other ways (mainly oral ways) of communicating to the public includes communication in conferences and seminars, oral reporting and broadcasting through radio or television *within China*.<sup>273</sup> It is similar to the practice in the US.<sup>274</sup>

In some cases, disclosure may not have been made explicit in a prior writing, but may be implicit therein. If the novelty test based only on explicitly disclosed information, then equivalents to an invention implicitly disclosed in the prior art can be novel. The result can be patenting of pieces of existing knowledge that are already contained in the prior art.<sup>275</sup> In China, inventions that can be directly deducted from information in prior art are considered lack of novelty.<sup>276</sup> Thus implicit disclosure in prior art can destroy the novelty of the invention. It is very similar to the patent practice of EPO.<sup>277</sup>

When comparing the invention in application with counterparts in prior art, China adopts the principle of separate comparison. Every claim shall be compared with respective technological information in prior art separately. Information in different publications shall not be combined together to destroy the novelty of the invention.<sup>278</sup> It is similar to the practice in the US.<sup>279</sup> However, in the inventive

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<sup>270</sup> Not including the filing date

<sup>271</sup> Publication is not restricted to written form, other media such as compact disc, cassettes, photographs etc, are also eligible as publication in China. See also the Guideline, part2 chapt3 sec2.1.3

<sup>272</sup> See Article 22.2 of the 2000 Amendment, *supra* note 20; confidential information does not belong to the “prior art”, see also the part 2 chpt. 3 sec. 2 of the Guideline, *supra* note 210

<sup>273</sup> See part 2 chpt. 3 sec. 2 of the Guideline, *supra* note 210

<sup>274</sup> In the US, disclosure that has taken place outside the US is only destructive of novelty when made in written form. See Carlos Correa, *Access to Plant Genetic Resources and Intellectual Property Rights, Commission on Genetic Resources for Food and Agriculture*, FAO, Background Study Paper No.8 (1999).

<sup>275</sup> See Bernd Hansen & Fritjoff Hirsch, *Protecting Inventions in Chemistry: Commentary on Chemical Case Law Under the European Patent Convention and the German Patent Law* 96 (VCH 1997)

<sup>276</sup> *Id* part 2 chpt. 3 sec. 3.2.1

<sup>277</sup> *Id*

<sup>278</sup> *Id* part 2 chpt. 3 sec. 3.1

step test, information in prior art shall be combined together in the mind of an average skilled person to destroy the patentability of the invention.<sup>280</sup>

In the pharmaceutical field, another important question is whether novelty would only be destroyed when the information in prior art enabled the execution of the invention, or whether a mere disclosure in the prior art would be sufficient.<sup>281</sup> It is very crucial issue concerning what kind of prior art may destroy the novelty of chemical substances in the pharmaceutical field.

In China, if information in prior art is sufficient enough to enable an ordinary skilled person to repeatedly obtain the same chemical compound or composition, the novelty of the compound or composition is thus destroyed. If the prior art cannot enable execution, even if there is complete information (name, structure and physical, chemical data) of a chemical substance, its novelty cannot be destroyed.<sup>282</sup>

### 5.2.2 Inventive Step

An invention, even if novel, is not patentable if its technical teaching could have been discovered in due course by a person with average skills in the respective field. Many countries' case law holds that there is no inventive step if it would be obvious for a person with average skills to test new matter with a significant likelihood of success. The inventive step or non-obvious requirement is critical to prevent the granting of patents to trivial inventions. It is the essential requirement to balance contribution and remuneration.<sup>283</sup>

The TRIP is not specific with the issue of inventive step. Article 27.1 of the TRIPS establishes that patents shall be granted to protect inventions, which "involve an inventive step" and in a footnote, it allows member countries to interpret "inventive step" as synonymous to "non-obvious."<sup>284</sup> A possible option for developing countries is to define and apply strict criteria for inventive step, in

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<sup>279</sup> The US requires complete disclosure in a single publication to destroy novelty, despite the fact that a skilled person may have been able to derive the invention without effort from a combination of publications. See Correa, supra note 103

<sup>280</sup> See 5.2.2 of this paper

<sup>281</sup> See Trevor Cook, Catherine Doyle & David Jabbari, *Pharmaceuticals Biotechnology & the Law* 79 (Stockton Press 1991), This was the approach adopted by the U.K. Patent law of 1977

<sup>282</sup> See the Guideline, part2 chpt 10 Sec.5.1 and 5.3

<sup>283</sup> See Correa, supra note 103

<sup>284</sup> See Article 27.1

order to avoid the granting of patents to trivial inventions that may unduly block competition in health-related products and processes.

In China, “inventive step” means that characteristics of the invention are not obvious to the average skilled person in the respective technology field.<sup>285</sup> Moreover, the invention should have corrected defects in respective technology of the prior art, be alternative technological method or representing the trend of technological development.<sup>286</sup>

In China, the average skilled person in a respective technology field is defined as a person that knows all relevant prior art and has the normal ability of experimenting and researching. However he has no ability of inventing.<sup>287</sup> In this way, the invention is compared with all prior art in the mind of the average skilled person. If the average skilled person is able to make the same invention, using logical analysis or limited experiments based on his knowledge of prior art and experimenting/researching ability, the invention thus has no inventive step. The inventive step test in China is almost exactly the same as the non-obvious test in the US.<sup>288</sup>

In establishing the existence of inventive step, it is necessary to consider not only the knowledge derived from a single prior document, but also the combined knowledge of existing literature, patent documents, and other prior art. In China, inventive step test adapts the principle of “combining comparison”. Respective technological information recorded in any document shall be compared with each claim in the application; all relevant technological information in the prior art shall be combined together to be compared with the respective claim in the invention.<sup>289</sup>

We should also notice that though the unexpected or surprising effect of the invention is considered a strong indication or evidence of inventive step in China, however it is not indispensable in the “inventive step” test.<sup>290</sup> On the other hand, the so-called “doctrine of sweat of brow” in the US patent practice is not applicable in China. The Guideline explicitly states that the inventive step test shall not consider whether the invention is achieved through painstaking laboring or it is simply serendipity.<sup>291</sup> China adapts an objective approach in the inventive step test.

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<sup>285</sup> Part 2 chpt. 4 sec 2.3 of the Guideline, supra note 210

<sup>286</sup> Part 2 chpt. 4 sec 2.4 of the Guideline, supra note 210

<sup>287</sup> Id part 2 chpt. 4 sec. 2.2

<sup>288</sup> See Jay Dratler Jr., *Intellectual Property Law, Commercial, Creative, and Industrial Property* §2.03[3] (Law Journal Press 1999) (1991)

<sup>289</sup> Id part 2 chpt. 4 sec.3.1

<sup>290</sup> Id part 2 chpt. 4 sec. 3.3.3

<sup>291</sup> Id



In the pharmaceutical field, there is often a close structural relationship between a compound that is claimed as new and inventive, and known compounds, such as salts of acids, bases, isomers, and homologues. In these cases, the new compounds are often deemed obvious thus not patentable.

In China, If a newly found chemical compound has the similar structure of any known compound, it should have unexpected use or effect to fulfill the inventive step requirement. On the other hand, if this chemical compound has totally different structure from all known compounds, unexpected use or effect is not required to pass the inventive step test.<sup>292</sup> It is the same practice as the EPO,<sup>293</sup> however different from the practice of the US.<sup>294</sup>

As for the use claim of chemical substances, it is divided into the use of known substance and unknown substances. The use of known substances shall have new function, positive effect based on the new function and also the function shall not be obviously obtained through the structure of the known substance. The use of unknown substance is easy to fulfill the inventive step requirement since only positive effect and that the use shall not be obviously obtained from *similar known substances* are required.<sup>295</sup> The rules for chemical substances are also applicable to micro-organisms and genes.<sup>296</sup>

### 5.2.3 Industrial Applicability

Patent law around the world aims to protect technical solutions to a given problem, not abstract knowledge. Thus inventions should be industrially applicable.<sup>297</sup>

Countries differ in their standards of industrial applicability. In U.S., certain developments that do not lead to an industrial product may be patented: an invention only needs to be useful.<sup>298</sup> This usefulness concept is broader than the "industrial applicability" concept that is required in Europe and other countries. The U.S. permits the patentability of purely experimental inventions that cannot be made or used in an industry, or that do not produce a technical effect,<sup>299</sup> as

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<sup>292</sup> Id part 2 chpt. 10 sec. 5.5

<sup>293</sup> See European Patent Office Technical Board of Appeal, T 154/82, IPD 7031

<sup>294</sup> See Grubb, *supra* note 229 at 195-196

<sup>295</sup> Id part 2 chpt. 10 sec. 5.4

<sup>296</sup> Id part 2 chpt. 10 sec. 7.6.2.1

<sup>297</sup> See Correa, *supra* note 103

<sup>298</sup> See [35 U.S.C. §101 \(1982\)](#)

<sup>299</sup> See David Bainbridge, *Intellectual Property* 270-72 (Pitman Publ'g 1992).

illustrated by the large number of patents granted in the U S on "methods of doing business." <sup>300</sup>

China uses the wording "usefulness" in its patent legislation instead of industrial applicability. The "Usefulness" in China means that the invention must be able to be manufactured or utilized in respective economic sections by the ordinary skilled person and has positive technological effect. The usefulness of the invention is examined before the novelty and inventive step test. <sup>301</sup> The invention shall be able to be repeatedly carried out by the ordinary skilled person. The results and technological effect should be the same or at least similar.<sup>302</sup> The "repeatability" requirement is essential part of the "usefulness" test. <sup>303</sup> For example, an invention that is created under unique natural environment and cannot be repeated by ordinary skilled person is not "useful" in China.<sup>304</sup>

The concept of usefulness in China is quite abroad, though not as abroad as the concept in the US. <sup>305</sup> Although the useful test in China requires technological effect, product invention manufactured in laboratory, not necessarily be industrialized, can qualify as useful. If the method invention can be utilized in respective economic section, not necessarily industrially applicable, use patent can be granted. <sup>306</sup>

TRIPS does not define the concept of industrial applicability and, therefore, leaves member states with considerable flexibility. <sup>307</sup> In order to avoid the proliferation of patents that may unduly jeopardize innovation and competition in the health sector, patent laws may provide as precise a concept of industrial applicability as possible. The broad "usefulness" concept used in China seems not suitable for a developing county. <sup>308</sup> Thus China had better raise its standard of usefulness. Product invention should be able to be turned into industrial products and method invention should be industrially applicable to pass the test of usefulness.

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<sup>300</sup> See *The Growing Flood of 'Wall Street' Patents*, PATNEWS (Sept. 29, 1994)

<sup>301</sup> Part 2 chpt.5 sec. 3 of the Guideline, supra note 210

<sup>302</sup> Id part 2 chpt.5 sec. 3.1(2)

<sup>303</sup> Id part 2 chpt. 5 sec. 3.2.1

<sup>304</sup> Id part 2 chpt. 5 sec. 3.2.2, 3.2.3 and 3.2.4

<sup>305</sup> US even does not require technological effect, see paragraph 2 of the 5.2.3

<sup>306</sup> Id

<sup>307</sup> It allows a member country to consider "capable of industrial application" as synonymous with the term "useful." See Correa, supra note 103

<sup>308</sup> See Carlos M Correa, supra note 103 at 27

## 5.2.4 Special Issues Relevant to Pharmaceutical Patents

Several issues relating to the application of patentability requirements may be specific to health-related inventions. WTO member countries retain a considerable degree of flexibility in addressing most of them. These issues may be appropriately treated in implementing regulations and guidelines for the patent office, rather than in the law itself.

Developing countries, particularly those for the first time patenting pharmaceutical inventions, should carefully design policy in these areas to ensure that patents are granted to real contributions to the prior art and to avoid granting patents to trivial invention. Poor drafting or administration of patent laws may impede competition and permit abusive practices that illegitimately extend patent protection beyond the twenty- year term required by the TRIPS.

### 5.2.4.1 Selection Patent

A "selection patent" is a patent under which a single element or a small segment within a large known group is "selected" and independently claimed, based on a particular feature not mentioned in the large group.<sup>309</sup> If the large group of elements is already patented,<sup>310</sup> the patent owner may use the selection patent to extend the term of protection beyond the expiration of the original patent, at least for the selected subset.

While accepted in some jurisdictions when the selected elements possess a surprising advantage, selection patents have been denied when the supposed advantage is a property shared by all or most subset of the large group.<sup>311</sup> An important policy issue is, therefore, to decide if and under which conditions selection patents should be admitted. TRIPS leaves full discretion to national laws in this area.

In China, the selection patent shall have unique feature and unexpected technological effect to fulfill the requirement of inventive step. Moreover, such unique feature and unexpected effect of the selection would not be logically inferred by the average skilled person from the information of the known large

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<sup>309</sup> A "selection invention" may take place, for example, when a range of products characterized as having N carbon atoms have been patented, and later on a patent on a specific range (e.g., C1-C4) is claimed. Substantial differences exist in the treatment of these patents, including between the EPO and some national offices in Europe. See Grubb, *supra* note 229

<sup>310</sup> Often broad (generic) patent claims are admitted, covering a large number (sometimes thousands) of possible compounds.

<sup>311</sup> See Grubb, *supra* note 229 at 197-199

group. Otherwise, the selection cannot fulfill the inventive step requirement.<sup>312</sup> The Chinese standard for selection patent is reasonably high. Not only a unique feature of the selection is required, but also the unique feature of the selection patent should not be obvious to an average skilled person.

#### **5.2.4.2 Analogy Processes**

Some countries have permitted patenting of non-novel processes, sometimes called analogy processes, provided that the resulting chemical substance is novel and displays unexpected properties.

The US has held "analogy process" claims to be unpatentable unless they are inventive in themselves,<sup>313</sup> but it has carved out an exception for biotechnology. The products and processes of biotechnology have posed problems for applying the inventive step standard, since many biotechnology "inventions" repeat previously invented processes in slightly different contexts. This problem led to a statutory amendment of U.S. law in 1995, which lowered the non-obvious standard by deeming a biotech process claim non-obvious if it involves new and non-obvious starting materials or produces a new and non-obvious result.<sup>314</sup>

While the protection of "analogy processes" has been accepted in many jurisdictions as a logical means of protecting new developments, no country is obliged under TRIPS to follow this approach of expanding the realm of patentable subject matter.

There is no explicit provision dealing with analogy processes in Chinese patent legislation. Thus the SPO should deal with analogy process in the traditional way. The resulting novel chemical substance can be patented. However the analogy process itself, since it is not novel, cannot be patented as process patent. As for analogy process in the biotechnology field, China should keep an eye on the practice of developed countries, however be cautious and critical to any radical practice.

### **5.3 Exceptions to Exclusive Rights**

All national patent laws contain exceptions to the exclusive rights granted by a patent. The content and scope of these exceptions vary widely. Some exceptions are particularly relevant to the health area. All of the exceptions considered below are recognized in some form in many developed countries. Article 30 of TRIPS treats the exceptions issue in general terms and leaves WTO member states with considerable freedom to define the nature and extent of exceptions.

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<sup>312</sup> See part.2 chpt. 4 sec. 4.3 of the Guideline, supra note 210

<sup>313</sup> Id at 206

<sup>314</sup> See Jay Dratler Jr, supra note 317

<sup>315</sup>Comparative law reveals that different types of exceptions may be provided for within the scope of article 30.<sup>316</sup> Outright exceptions to the exclusive rights of a patent, which operate without the need of specific authorization by a court or other authorities, and in favor of any third party, may be extremely important in fostering innovation, promoting the diffusion of technologies or facilitating access to health-related goods at the lowest possible prices.

Exceptions of exclusive rights are even more important than all strategies we have provided in the parts of patent subject matters and patentability. Subject matters and patentability shall be applied to local and foreign inventions on equal basis. As for the exceptions, many of them, like compulsory license and parallel importation, maybe applied in a way that is in favor of the local industry, provided that the legislation itself is not discriminatory. Experimental use and early working could be used by the local industry in a proper way competing with the foreign pharmaceutical industry. The latter has been substantiated even in the practice of the Chinese pharmaceutical industry.

### 5.3.1 Experimental Use

A basic objective of the patent law is to promote innovation. However, overly broad patent rights may harm innovation.<sup>317</sup> One mechanism to address the problem is permitting the use of the invention without compensation to the owner for experimentation. Experimental use may foster technological progress based on "inventing around" and improving protected invention. It also permits evaluating an invention in order to grant a license, or for other legitimate purposes, such as to test whether the patent is valid.<sup>318</sup> Although the experimental use is rather narrow in the US,<sup>319</sup> many countries, notably in Europe, explicitly authorize experimenting on an invention without the consent of the patent holder, for scientific purposes.<sup>320</sup>

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<sup>315</sup>See TRIPS art. 30 supra note 70.

<sup>316</sup> See Correa, supra note 103, at 34

<sup>317</sup> See Roberto Mazzoleni & Richard Nelson, *The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate*, 27 Res. Pol'y 275 (1998)

<sup>318</sup> See Rebecca Eisenberg, [Patents and the Progress of Science: Exclusive Rights and Experimental Use](#), 56 U. Chi. L. Rev. 1017 (1989); David Gilat, 11C Studies, Experimental Use and Patents 16 (VCH 1995)

<sup>319</sup>Harold Wegner, *Patent Law in Biotechnology, Chemicals & Pharmaceuticals* 267 (Stockton Press 1994 )

<sup>320</sup> See William R. Cornish, *Experimental Use of Patented Inventions in European Community States*, 29 Int'l Rev. Indus. Prop. & Copyright L. 735, 736 (1998)

The 2000 Amendment explicitly provides that “using relevant patents *exclusively for the purpose of* scientific research and experiments shall not be deemed as infringement of the exclusive rights of the patent holder”.<sup>321</sup> No further explanation on this issue exists in the Implementing Regulation or in the Guideline. At least, however, we may deduct from the wording of “exclusively for the purpose of” that experimental use shall not be used for commercial purpose when the patent has not expired.

Whether the experimental user should obtain the authorization of the patent holder is not clear in China. According to the general practice in different domestic patent legislations, authorization for experimental use is not practicable and not necessary, since experimental use will not affect the patent holder’s exclusive rights of commercial exploitation. Thus we are inclined to suggest that for experimental use in China one need not obtain the authorization of the patent holder.

However, whether the result of the experimental use can be used for commercial purpose after expiration of the patent still remains as a question in Chinese patent legislation. This question relates to the issue “early working” and shall be discussed in 5.3.2 of this paper.

### **5.3.2 Early Working**

Another exception specifically applicable to pharmaceutical patents is early working: using an invention without the patentee’s authorization for the purpose of obtaining approval of a generic product before the patent expiration date. Early working may permit marketing of a generic version of the product promptly after the patent expires. Since generic competition generally lowers prices,<sup>322</sup> this exception promotes the affordability of off-patent medicines. The availability of generics either under a brand name (branded generics) or a generic name (commodity generics) would lead to increased competition in the pharmaceutical market, and to correspondingly lower prices for the consumers and improved affordability of drugs.<sup>323</sup>

Given that commercialization of the generic product does not take place until after the expiration of the patent, the early working exception can be regarded as fully compatible with article 30 of TRIPS. In the case of Canada, the law provided for

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<sup>321</sup> Article 63.4 of the 2000 Amendment, *supra* note 20

<sup>322</sup> See World Health Organization, *The World Drug Situation* 31 (1988)

<sup>323</sup> *Id*

early working that not only allows tests with the invention, but also producing and stockpiling of the product for release immediately after the expiration of the patent.<sup>324</sup> The European Union requested a panel against Canada under the WTO dispute settlement mechanism in connection with this exception. The panel decision confirmed that an early working exception is consistent with TRIPS. However, the panel considered that the right to manufacture and stockpile before the expiration of the patent was not consistent with TRIPS.<sup>325</sup> Manufacturing and stockpiling products are commercial exploitation in conflict with the exclusive rights of the patent holder. Thus it was reasonable for the panel to rule that the Canadian early working system, which allows even manufacturing and stockpiling, was partly inconsistent with the TRIPS.

The "early working" exception, as noted in 5.3.1, may in some cases be considered as one type of experimental use exception. If the result of experimental use is used for future commercial exploitation, namely commercial exploitation after the expiration of the relevant patent, it may have the same function as early working. Chinese patent legislation has not touched on the issue of early working. Although China may permit using the result of the experimental use for commercial purpose after expiration of the patent, given the importance of early working in fostering national pharmaceutical industry and lowering medicine price, Chinese legislators should add a specific provision on early working.

### **5.3.3 Parallel importation**

Parallel importation involves the importation and resale in a country, without the consent of the patent holder, of a patented product, which was put on the market of the exporting country by the patent holder or in other legitimate manner. For example, a company may buy a patented machine sold in Germany and then resell it in Canada, where the same patent is in force, without the patent holder's authorization.

Parallel importation is the second most important measure developing country may make use of when dealing with public health crisis. This part of the paper shall analyze the theoretical basis for parallel importation and its economic implication first. Then relevant Chinese legislation shall be analyzed in connection with the theoretical basis, the requirement of TRIPS and the model provisions in the MRSCAA of South Africa.

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<sup>324</sup> See Canada Patent Act §55(2)(2) (1993)

<sup>325</sup> See WT/DS114/R (Mar. 17, 2000) (Canada-Patent protection of pharmaceutical products).

### 5.3.3.1 Doctrine of Exhaustion and its Economic Implication

The underlying concept for allowing parallel importation is the Doctrine of Exhaustion. Since the inventor has been rewarded through the first sale or distribution of the product, he/she has no right to control the use or resale of goods put on the market with their consent. In other words, the inventor's rights have been "exhausted."<sup>326</sup> If the patent holder put the patented products in no matter which country in the world and the patent concerned is exhausted, it is called "international exhaustion". If only marketing the patented products in a particular region may exhaust the patent, marketing the patented products outside of this region may not exhaust the patent, it is called "regional exhaustion". Also we should bear in mind that parallel importation, where allowed, cover only legitimate products, not counterfeited products or unauthorized products that are put in a foreign market.<sup>327</sup>

Parallel importation has been admitted in many developed and developing countries, on a regional or international scale, for all or some areas intellectual property rights. For instance, in the European Communities (EC) the European Court of Justice has applied the doctrine of regional exhaustion of rights to the entire EC and to different types of intellectual property rights, in order to prevent market segmentation. Once a patented product has been sold in an EC country, it can be resold in any other member country without infringing the right holder's rights. Another example is South Africa. South Africa establishes its parallel importation system based on the international exhaustion dealing with public health crisis under Section 15 (c) (b) of the MRSCAA.<sup>328</sup>

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<sup>326</sup> The doctrine of "exhaustion of rights" may be applied at the national level (rights are deemed exhausted domestically and the commercialization in foreign countries is not deemed to have exhausted the patentee's rights), at the regional level, as in the case of the European Community (exhaustion is deemed to have occurred if commercialization took place in a country member of a regional agreement), or at the international level. The presentation made in the text refers to this latter case.

<sup>327</sup> Abundant literature and considerable case law (particularly in the European Community) exists on the doctrine of exhaustion and parallel importations. See Frederick Abbott, First Report (final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel importation, 1 J. Int'l Econ. L. (1998)

<sup>328</sup> In the case of the United Kingdom, however, the principle of international exhaustion has been admitted in some cases. The European Court of Justice has accepted parallel importations even in cases where the product was not protected by a patent in the exporting country. See Case 267/95, Merck & Co. v. Primecrown Ltd. (Dec. 1996)



In economic terms, the acceptance of parallel importation may prevent market segmentation and price discrimination by patent holders on a regional or international scale. In other words, parallel importation allows consumers to shop on the world market for the lowest price for a patented good effectively.<sup>329</sup> Parallel importation is particularly important in the health sector, where the pharmaceutical industry sets prices differently throughout the world for the same medicine. Importation of a patented medicine from a country where it is sold at a lower price will enable more patients in the importing country to gain access to the product, without preventing the patent owner from receiving remuneration for the patented invention in the country where the product was first sold.

On the negative side, states must evaluate the argument that there is an economic risk that the doctrine of exhaustion may discourage price differentiation favoring the developing countries. It has been argued that if parallel importation were to be admitted generally, companies would tend to charge a single price worldwide, leading to an increase in the supposedly lower price that may otherwise be charged in low-income countries.<sup>330</sup> The pharmaceutical industry is concerned with cross-market leaks that could reduce its profit margins and thereby its ability to recoup R&D investments. For these and other reasons, states need to carefully monitor the actual implementation of their exhaustion policy.

### **5.3.3.2 Chinese Legislation Concerning Parallel importation**

As I have analysed in the 3.4 of this paper, TRIPS allows member states to adopt parallel importation and leaves all issues concerning “exhaustion” to the discretion of the domestic legislators.

In China, the 2000 Amendment grants a wide range of exclusive rights to the patent holder, “...except provided otherwise in this law, without the authorization of the patent holder, any Unit (danwei) or individual shall not work the patent, namely, shall not manufacture, use, offer for sale, sell, import the product protected under the patent for commercial purpose, or use the patented process or use, offer for sale, sale, import products that are directly manufactured through the patented process.”<sup>331</sup>

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<sup>329</sup> In some countries, laws have established regulations providing for exclusive licensing agreements for the importation and distribution of goods. These kind of regulations restrict competition and practically impede parallel importation.

<sup>330</sup> However, price levels are generally established in different countries according to the consumers' ability to pay. Hence, the setting of a single world price may be not be economically viable.

<sup>331</sup> Article 11 of the 2000 Amendment, *supra* note 20

Regarding the doctrine of exhaustion, 1992 Patent Law only provides, “ After the first sale of the products that are manufactured, imported by the patent holder or authorized to be manufactured or imported by the patent holder, or after the first sale of products manufactured through the patented process, using, offering for sale or selling of these products shall not be deemed as infringement of the exclusive rights of the patent holder.”<sup>332</sup>

There are at least two main defects in provisions concerning exhaustion and parallel importation in the 2000 Amendment. First, the “first sale” mentioned in the provision of “exhaustion” is first sale in any place in the world or only within a certain region has not been made clear. From the perspective of facilitating parallel importation, we should interpret the “first sale” as “first sale in any place of the world”. In other words, we should adopt “international exhaustion”. Secondly, after the first sale, only “using, offering for sale or selling” of patented products shall not be deemed as infringement of the exclusive rights of the patent holder. Importation of patented products has not been included in the rights that have been exhausted by the first sale. It is reasonable to surmise that Article 63(1) implies that even after the first sale of the patented products, importing of these products that are legitimately put on foreign markets shall still be subject to the consent of the patent holder. Article 63(1) of the 2000 Amendment has excluded the possibility of parallel importation in China. We should include importation in rights that are exhausted by the first sale.

Even so, the Chinese government may still import patented products in need under certain grounds of compulsory license, such as state emergency or public interests, because importation patented products could be one way of carrying out compulsory license. This method shall be discussed in 5.4.4.6 of this paper. However, this kind of importation is not parallel importation since it is not based on the exhaustion of the patent.

### **5.3.4 Compulsory License**

Compulsory license enables a government to license the right to use a patent to a company, government agency or other party without the patent holder's consent. A compulsory license must be granted by a competent authority to a designated person, who should generally compensate the title-holder through payment of remuneration. Compulsory licenses do not deny patent holders the right to act against non-licensed parties.

The provision of compulsory licenses is a crucial element in a health- sensitive patent law. Such licenses may constitute an important tool to promote competition and increase the affordability of drugs, while ensuring that the patent owner

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<sup>332</sup> Id article 63.1

obtains compensation for the use of the invention. The use of such licenses, however, has been generally opposed by the research-based pharmaceutical industry, on the grounds that they discourage investment and R&D.<sup>333</sup>

Most countries, including developed countries, make available some forms of compulsory licenses.<sup>334</sup> Such licenses are one of the mechanisms that states can use in order to promote competition and access to drugs. Although it is advisable that national laws provide for a compulsory licensing system (as further elaborated below), it should be borne in mind that such a system is not intended to, and cannot fix problems arising from the defective granting of patents, such as when the novelty or inventive step requirements are not satisfied. It is of crucial importance to ensure that the patentability criteria are rigorously defined and applied in the pre-grant process.

Compulsory licenses are generally available for lack or insufficiency of working,<sup>335</sup> to remedy anticompetitive practices, for cases of emergency, governmental or "crown" use, and for other public interest grounds. Grounds of granting compulsory license are not restricted to these that have been mentioned in the TRIPS. Most developed countries provide for grounds of using compulsory licenses. Many developing countries that have recently revised their patent laws have also defined a more or less comprehensive list of reasons for granting compulsory licenses.<sup>336</sup>

#### **5.3.4.1 Compulsory License in Chinese Patent Legislation**

There are three grounds of granting compulsory license in the Chinese Patent Law. First, when a Unit (Danwei) has made efforts to obtain authorization from the patent holder on reasonable commercial terms and conditions and has not obtained authorization within a reasonable period of time, the Patent Bureau may grant compulsory license to the Unit.<sup>337</sup> Secondly, when there is state emergency, special situation or for the sake of public interests, the Patent Bureau may grant

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<sup>333</sup> On the impact of compulsory licenses on R&D in the United States, see F.M. Scherer, *Comment, in Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* 104 (Robert Anderson & Nancy Gallini eds., Univ. of Calgary Press 1998)

<sup>334</sup> See Carlos Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* (South Centre, Geneva, Working Paper No. 5 1999)

<sup>335</sup> "Working" of a patent was originally understood as the execution of the invention in the country of registration, see Penrose, *supra* note 8. The current trend in some countries is to admit that working may take place through importation. Article 27.1 of TRIPs has been interpreted by some (notably the research-based pharmaceutical industry) as excluding the possibility of requiring the local execution of the invention. See, however, the Brazilian Patent Law (1996), which established that such obligation was incurred only if economically viable. See Brazilian Patent Law art. 68.1 (1986)

<sup>336</sup> See Correa, *supra* note 364

<sup>337</sup> Article 48 of the 2000 Amendment, *supra* note 20

compulsory license.<sup>338</sup> Thirdly, if a new patent, which is of significant commercial value and inventive step, whose exploitation has to be based on exploitation of a former patent, the Patent Bureau has the right to grant compulsory license upon application of the new patent holder. The first patentee is entitled to cross-license on reasonable terms.<sup>339</sup>

These three grounds of granting compulsory license are submitted to procedural restrictions: When granting compulsory license, the Patent Bureau is obliged to notify the respective patent holder. Each compulsory license shall have its scope and duration. When the causation of the compulsory license terminates, the Patent Bureau should terminate the compulsory license upon application of the patent holder.<sup>340</sup> Furthermore, the rights of the compulsory licensee are non-exclusive and not assignable.<sup>341</sup> Reasonable remuneration to be paid to the patent holder is a must and should be based on negotiation between the patent holder and the licensee.<sup>342</sup> Any Unit may apply for compulsory license three years after the granting of any patent.<sup>343</sup> The exploitation of the patent under a compulsory licensing shall predominantly be for the purpose of fulfilling the demands of domestic market.<sup>344</sup>

Either the compulsory license or the remuneration is subjected to judicial challenge. Disputes over compulsory license or its remuneration is first subject to administrative arbitration of the Patent Bureau and then subjected to judiciary decision of respective People's Court.<sup>345</sup>

No provision concerning compulsory license exists in the pharmaceutical administrative protection regime.

#### **5.3.4.2 More Grounds needed**

As presented above, only three grounds are provided for granting compulsory license in China: (1) the failure of obtaining licensing under the reasonable commercial terms; (2) exploitation of a new patent that is based on the previous patent; (3) in the public emergency or for the public interests. Comparing with Article 31 of TRIPS, it is obvious that these grounds are copies of respective provisions in the TRIPS.

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<sup>338</sup> Id Article 49

<sup>339</sup> Id Article 50

<sup>340</sup> Id Article 52

<sup>341</sup> Id Article 53

<sup>342</sup> Id Article 54

<sup>343</sup> Id Article 72 para. 1

<sup>344</sup> Id Article 72 para. 4

<sup>345</sup> Id Article 55

In our view, it is not wise for the Chinese legislators to provide only three grounds that are explicitly exemplified in the TRIPS. TRIPS does not require that these grounds are acceptable. Other grounds of granting compulsory license, if they comply with conditions in article 30 and 31 of TRIPS, are also acceptable.<sup>346</sup>

As we have seen in the 1970 Indian Patent Act and South Africa MRSCAA, grounds for granting compulsory license are different from those provided in the TRIPS.<sup>347</sup> In India, if the patent could not fulfill the reasonable demand of the public, compulsory license may be granted.<sup>348</sup> In South Africa, if there is a public health crisis, the Ministry of Health may take all measures necessary to obtain affordable drugs to relieve the crisis. Compulsory license may be granted and parallel importation may be authorized.<sup>349</sup> Both grounds are provided in an abstract way so that the government may fit different situations into them.

Public non-commercial use and correcting anti-competition practices are another two widely accepted grounds that TRIPS allows however cannot be found in the Chinese patent law. Besides adding new grounds for compulsory licensing, the people's court may also interpret abstract ground such as "public interests" in a flexible way.

#### **5.3.4.3 Discrimination or Differentiation**

Addressing public health crisis through compulsory license have existed in domestic legislations for long time.<sup>350</sup> Mainly there are two different approaches. First, national legislations explicitly grant governments the authority of granting compulsory license when public health crisis rises. Thus compulsory license is directly relating to pharmaceutical patents. The South Africa compulsory license system addressing the AIDS/HIV crisis established by the MASCAA is a typical example.<sup>351</sup> In the second approach, public health crisis or demand for affordable medicine is not the specific ground for granting compulsory license. Grounds such as state emergency or public interests are broadly interpreted to include public health crisis. In this way, the ground for compulsory license is not directly in relation to pharmaceutical patents. The test of "reasonable demand of the public" in the 1970 Indian Patent Act is an example. When public health crisis rises, working of certain patents may be deemed as having not met the reasonable demand of the public. So a compulsory license maybe justified.<sup>352</sup>

In the TRIPS, all grounds of granting compulsory license shall be subject to non-discrimination provision-Article 27(1). Grounds having the effect of discrimination

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<sup>346</sup> See Article 30 and 31 TRIPS, see also 3.3 of this paper

<sup>347</sup> See 4.1.1 and 4.2.2 of this paper

<sup>348</sup> Id see 4.2.2

<sup>349</sup> Id see 4.1

<sup>350</sup> See Correa, supra note 103

<sup>351</sup> See 4.1.1 of this paper

<sup>352</sup> See 4.2.2 of this paper

shall be prohibited under TRIPS. Compulsory license system directly dealing with the public health crisis, like the one established by the MRSCAA in the South Africa, is very likely to be challenged by the pharmaceutical industry as discrimination, since in dealing with public health, pharmaceutical patents are most likely to be licensed.<sup>353</sup>

This problem has already been solved by the DSB in the Canadian Case. The panel makes it clear that first, not all differentiation on grounds of granting compulsory license is prohibited. Only those of a discriminating effect are prohibited. Secondly, specific compulsory licensing system in relation to public health crisis *could be* bona fide system that has no discrimination effect, though they are always specifically in relation to pharmaceutical patents. The holding of the Panel makes it clear that even the compulsory license system directly in relation to the pharmaceuticals is not necessarily to be deemed as discriminatory<sup>354</sup>

Chinese patent legislation has not granted the government the authority of granting compulsory license when a public health crisis arises. However, emergency and public interests are established grounds for compulsory licensing in the patent law.<sup>355</sup> It is recommended to adopt the second approach mentioned above, namely, including public health crisis as a ground of the emergency.

#### 5.3.4.4 Correcting Anti-Competition Practice

Article 40 of the TRIPS allows member states to take measures necessary to deal with the anti-competition practices in relation to abusing intellectual property rights.<sup>356</sup> Compulsory license could be an effective measure in correcting anti-unfair competition practices such as exclusive grant back conditions, conditions preventing challenges to validity and coercive package licensing.<sup>357</sup> The practice of using compulsory license correcting anti-unfair competition has long been existed in national legislations.<sup>358</sup> Though relatively little compulsory license has been granted in this regard,<sup>359</sup> the practical value of the existence of compulsory license provisions in the Patent Law is that it has a threatening effect. It usually

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<sup>353</sup> See 3.3 and 4.1 of this paper

<sup>354</sup> See 3.3 of this paper

<sup>355</sup> Article 49 of the 2000 Amendment, *supra* note

<sup>356</sup> Article 40 of TRIPS, *supra* note 70

<sup>357</sup> *Id*

<sup>358</sup> See [42 U.S.C. §7608 \(2000\)](#) (U.S. Clean Air Act); *id.* §2183 (Atomic Energy Act 1988).

<sup>359</sup> The largest number of compulsory licenses in Canada have been issued under the 1969 amendment that authorized automatic licenses on pharmaceuticals. In the United States, most compulsory licenses have been issued under antitrust laws. See Correa, *supra* note 102

induces the grant of contractual licenses on reasonable terms, and thus the objective of actually working the invention is accomplished." <sup>360</sup>

Unfortunately, the Chinese anti-unfair Competition law has not made use of Article 40 of TRIPS. It has not touched the issue of anti-unfair competition practices in relation with abusing the patent or other intellectual property rights. <sup>361</sup>Besides the ground of public interests for compulsory license in the Chinese Patent Law, which maybe temporarily used to deal with anti-competition practices, China also needs the particular ground of correcting anti-competition practices. In our view, the reasons lie in three aspects. First, Compulsory license granted on the ground of correcting anti-competition practice need not to be submitted to the restriction in (b) and (f) of Article 30 TRIPS. <sup>362</sup> This point has been clarified in 3.3 of this paper. Secondly, as we know, China is on the way towards establishing a socialist market economy. Enhancing legislations guaranteeing a fair and healthy market environment is especially important in this process. Thirdly, since most of the pharmaceutical patents in China are held by large multinational enterprises, the multinational enterprises are very likely to unduly take advantage of their dominant market position. From the perspective of protecting immature national pharmaceutical industry, China should consider regulating anti-competition practices relating to abusing patent rights by foreign competitors.

#### **5.3.4.5 Working Requirement and Local Working Requirement**

“Working requirement” means that if a patent is not worked by the patent holder and the patent holder also has not authorized other people to work it in a reasonable period, the government may grant compulsory license on the patent. “Working requirement” has not been prohibited by the article 30 and 31 of the TRIPS. <sup>363</sup> Also in the article 5 of the Paris Convention, “lack of working” is the only exemplified ground of granting compulsory license, provided there has been a grace period of three or four years. <sup>364</sup>

Some domestic patent legislations, such as the 1970 Indian Patent Act, further requires that the patent should be locally worked to fulfill the demand of the domestic market. Under 1970 Indian Patent Act, if patent that has been granted has not been sufficiently worked in India, even though importation is used to fulfill the reasonable demand of the general public, compulsory license also could be

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<sup>360</sup> See Friedrich- Karl Beier, *Exclusive Rights, Statutory Licenses and Compulsory Licenses in Patent and Utility Model Law*, 30 Int'l Rev. Indus. Prop. & Copyright L. 251, 260 (1999)

<sup>361</sup> Law Against Unfair Competition of the People's Republic of China (Unfair Competition Law), promulgated on September 2, 1993, effective December 1, 1993, [www.iplaw.pku.edu.cn/law/8126.htm](http://www.iplaw.pku.edu.cn/law/8126.htm)

<sup>362</sup> See article 31 of TRIPS, supra note 70, see also 3.3 of this paper

<sup>363</sup> Article 31 of the TRIPS, supra note 70

<sup>364</sup> Article 5 of the Paris Convention, supra note 26

granted to the domestic industry.<sup>365</sup> The legal measure could be called “local working requirement”.

However, the far-reaching non-discrimination clause -Article 27 (1) of TRIPS provides, “...patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”<sup>366</sup> Whether the “local working requirement” in the 1970 Indian Patent Act is discrimination between “products imported or locally produced “is not clear. In our opinion, if the patent holder simply intends to use the patent to prevent domestic industry from producing similar products, namely he has not worked the patent locally and even has not imported the products, thus the demand of the domestic market has not been met, the government may grant compulsory license to a local industry. If the patent holder has not worked the patent locally, however has imported products to fulfill the demands of the domestic market, it seems that the government has no right to grant a compulsory license, since there are imported products to meet the demand of domestic market and Article 27(1) provides that patent rights shall be enjoyed without discrimination as to imported products or locally produced counterparts. Thus “local working requirement” in the 1970 Indian Patent Act is *partly inconsistent* with the TRIPS, according to our analysis.

In the 1984 Chinese Patent Law, “local working requirement” existed. However, upon the amendment in 1992, there is no “local working requirement” nor does “working requirement” exist. In the pharmaceutical administrative protection regime, there is no “working requirement”.<sup>367</sup> Before the TRIPS came into force to India, the generic pharmaceutical industry in India benefits a lot from the provision of the “local working requirement”. TRIPS shall enter into force to China at the end of 2002. In the series of intellectual property agreements between US and China, there is no provision restricting the use of “working requirement”. We suggest that Chinese legislators may authorize the government to grant compulsory license when working of certain patents is not enough to meet the demand of domestic market. In compliance with Article 27 of the TRIPS, if the patent holder has imported products to meet the demand of the domestic market, the compulsory license should not be granted.

#### **5.3.4.6 Importation and Exportation under Compulsory License**

TRIPS has not eliminated the possibility that a compulsory license may be executed by means of importing patented products.<sup>368</sup> This may, in fact, be the

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<sup>365</sup> See 4.2.2 of this paper

<sup>366</sup> Article 27.1 of TRIPS, *supra* note 70

<sup>367</sup> See 2.3 of this paper

<sup>368</sup> The importation of the product was a key element in the Canadian compulsory system mentioned above, as revised in 1969. See *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy* 65 (Robert Anderson & Nancy Gallini eds., Univ.



only viable means to execute a compulsory license in cases where the capacity of the local market does not justify local working, or where there is a need to promptly address emergent situation like public health crisis.

The Chinese Patent Legislation does not provide specific ways of executing compulsory license. According to 2000 Amendment, Unit that has qualified competence may obtain compulsory license from the Patent Bureau to *make use of* the patent.<sup>369</sup> The law has not clarified in what way the compulsory licensee may make use of the patent. May the licensee import patented products instead of manufacture them? The ambiguity of the law grants the government flexibility to allow compulsory licensee to import patented products concerned. As analyzed in 5.3.3.2 of this paper, the possibility of parallel importation under current Chinese patent legislation has been eliminated by defects in the exhaustion provision.<sup>370</sup> Thus importing patented products under compulsory license appears to be even more important.

A further question is whether a compulsory licensee may export licensed products. TRIPS provides that compulsory license must be "predominantly" for the purpose of supplying domestic market.<sup>371</sup> The Implementation Regulation of the 1992 Patent Law has the same provision as those in the TRIPS.<sup>372</sup> Thus, exports of licensed products are possible in China, though it should not constitute the main activity of the licensee. We should also note that, the "predominantly for domestic market" restriction, however, may not apply when a compulsory license has been granted to remedy anti-competitive practices.<sup>373</sup>

Since compulsory license dealing with public health crisis are most possibly used to supply the demands of the domestic market, the possibility of exporting licensed products by the licensee, however, does not seem to be in line with the objective of dealing with public health crisis.

#### **5.3.4.7 Public Non-commercial Use**

Public non-commercial use is the use of the compulsorily licensed patent by the government or contractor for non-commercial purposes. Addressing public health crisis is a typical reason for launching public non-commercial use. According to TRIPS, in the case of public non-commercial use, the restriction of "reasonable commercial term" on compulsory license maybe waived, provided the patent

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of Calgary Press 1998). If the compulsory licensee imported legitimate products (sold in a foreign country by the patent holder or with his consent), its acts could be covered under an exception for parallel importations.

<sup>369</sup> Article 48 and 50 of the 2000 Amendment, *supra* note 70

<sup>370</sup> See 5.3.3.2 of this paper

<sup>371</sup> See TRIPS *supra* note 70, art. 31(f).

<sup>372</sup> See Article 72 para. 4 of the Implementing Regulation, *supra* note 212

<sup>373</sup> *Id* 31(k)

holder is promptly notified. Moreover, according to the practice in the US, domestic legislation may eliminate a patent owner's right to seek an injunction to bar the government or a government contractor from using its patent, allowing the patent owner only the right to seek compensation.<sup>374</sup>

There is no provision in the Chinese Patent legislation dealing with public non-commercial use, no matter the patent is used by the government or contractors. In judicial practice in China, compulsory license that is actually for public non-commercial use has been granted on the grounds of state emergency or other situations of extreme emergency.<sup>375</sup> However, as we have seen in TRIPS, public non-commercial use is a specific ground of granting compulsory license other than the ground of emergency. It is suggested that China make use of this ground. Public non-commercial use is also a ground that bears less procedural restriction than other grounds of compulsory license in the TRIPS. Currently in China, all compulsory licenses are subject to the restriction of “reasonable commercial terms”.<sup>376</sup> Thus China especially needs a ground such as non-commercial use, which may not be restricted by the “reasonable commercial terms”.

#### 5.3.4.8 Remuneration

TRIPS only requires “adequate remuneration” and “take into account the economic value of the authorization” when deciding the remuneration to the patent holder.<sup>377</sup> In general, certain remuneration may be established on the basis of the rates generally applicable in the respective industrial sector.<sup>378</sup> Another possibility is to define a “reasonable” remuneration as which a third party would pay for a voluntary license. The latter method, introduced by U.S. law in 1922, has been extensively applied in U.S. case law relating to the infringement of patent rights.<sup>379</sup> In the case of compulsory licenses for U.S. governmental use, however, remuneration is based on what the patent holder has lost, not on what the licensee has gained.<sup>380</sup>

The practice in Canada (while a system of compulsory licenses was in force) was to require remuneration of four percent of the sales price of medicines under

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<sup>374</sup> See 28 U.S.C. §1498 (1994) (U.S. Executive Order 12889 regarding the implementation of NAFTA)

<sup>375</sup> Article 49 of the 2000 Amendment

<sup>376</sup> Article 48,49 and 50 of the 2000 Amendment

<sup>377</sup> Article 31(h) TRIPS, supra note 70

<sup>378</sup> See Argentine Patent Law, art. 43 (1995)

<sup>379</sup> See Donald Chisum, *Patents* P20.02.2 (Matthew Bender 1992)

<sup>380</sup> See the U.S. decision in [Leesona Corp. v. United States, 599 F.2d 958, 969 \(1979\)](#).

license. In India, the applicable policy guidelines normally limit remuneration to a maximum of four percent of net sales.<sup>381</sup>

In order to determine compensation, authorities may require the patent holder to disclose product-specific R&D investments, revenues and other relevant economic data, while ensuring adequate protection of any confidential commercial data. They may also take into account the domestic market share in the total world market for the licensed product, in order to determine what proportion of actual cost of the R&D the country should pay. In commercial practice, remuneration usually range from 0.5% to 10% of the net sales of the licensed product, depending on the market volume and turnover of the specific product,<sup>382</sup> and depending on the stage of the technology in the life cycle, among other factors.<sup>383</sup>

Chinese patent law only requires that the remuneration be reasonable and based on negotiation. In accordance with the TRIPS, remuneration for compulsory license may be subject to judicial review in China.<sup>384</sup> The patent law provides no specific formula to decide what is reasonable remuneration.<sup>385</sup> It is suggested that China should decide the remuneration according to the reasonable rate in the respective industrial sector, as the general practice in most countries. At the same time, a maximum limit should be set in case of extreme market situation. Compulsory license for public non-commercial use should be remunerated in accordance with the loss of the patent holder, as the practice in the US.

#### 5.3.4.9 Duration

The duration of a compulsory license is important. If the term is too short, there may be no incentive for a third party to request or accept a license. The general practice is that compulsory licenses should be granted for the remaining term of the patent. This is the solution in general, except when the compulsory license is granted on the grounds of emergency or public interests. In the case of emergency or public interests, the compulsory license is to be terminated when the extreme situation, such as public health, has ended.<sup>386</sup>

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<sup>381</sup> See David Graber, *Foreign Countries' Licensing Practices* (cited in USTR's Annual Trade Barriers Report), *World Licensing Law Report/BNA*, No. 4, at 3 (1999)

<sup>382</sup> See Peter Niess, *Technology Evaluation and Pricing*, *Tech. Monitor*, Nov.-Dec. 1999, at 16-17

<sup>383</sup> See Vinay Kumar & Jyotti Bhat, *Estimating Payments for Technology: A Framework for SMEs*, *Tech. Monitor*, Nov.-Dec. (1999)

<sup>384</sup> *Id.*, see also Article 31 (j) TRIPS, *supra* note 70

<sup>385</sup> Article 54 of the 2000 Amendment, *supra* note 20

<sup>386</sup> See Carlos E Correa, *supra* note 103 at 50

In China, the duration of compulsory license should be determined in accordance with its different grounds. Moreover, if the situation that the compulsory license addresses ends, the compulsory license can be terminated upon application of the patent holder, provided the situation is not likely to happen again.<sup>387</sup> It provides no general duration for a compulsory license. I suggest that in general, compulsory license in China should be granted for the duration for the remaining term of the patent.

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<sup>387</sup> See Article 52 of the 2000 Amendment, *supra* note 20, The latter restriction on the duration of compulsory license only apply to those granted on the ground of emergency or public interests.

## 6 Conclusion

The evolution of Chinese patent legislation has been under constant pressure from the US. However, China is not the only developing country under such pressure. India, South Africa, Thailand and Brazil, among which the latter two have not been discussed in this paper, are all developing countries facing severe threats of trade sanction from the US. India and South Africa have struggled hard and fruitfully for bringing about a national legislation that can foster national pharmaceutical industry or may efficiently address public health crisis. Though China has much more interaction with the US in intellectual property protection, it has not taken much initiatives struggling with US in consideration of national pharmaceutical industry or public health.

Although TRIPS is great success for developed countries, flexibility still exists in this agreement for a developing country to take advantage of. As analysed in part 3 of this paper, certain provisions in TRIPS, together with the Doha Declaration, leave adequate room for a developing country to establish a public-health-friendly patent protection system.

Chinese Patent Legislation currently in force complies with the TRIPS requirement. Actually, the 1992 Amendment of Patent Law, under the pressure of 1992 MOU, has already reached the protection level of TRIPS. In addition, the pharmaceutical administrative protection regime protects foreign pharmaceutical patents granted between 1984 and 1993. So what China needs to consider now therefore is not how to comply with the TRIPS but how to make use of the flexibility of the TRIPS in the public health concern.

China has not made full use of the flexibility provisions in the TRIPS. Even worse, some of the provisions are a direct copy of the TRIPS or the practice of the US, which eliminates the possibility to be flexible. Chinese scholars are eager to comply with advanced standards of patent protection advocated by developed countries. However they are rarely willing to stand on the side of developing countries. Thus the patent protection system in China needs adjustment in different aspects, from patentability to exceptions to exclusive rights, bearing in mind the public health concern and making use of the flexibility of the TRIPS. This theme is what my thesis has tried to make a contribution towards.

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