

Wednesday, October 21 9:00 am–10:30 am

309 Orienting East: IP in China

Bonita Lewis Bell *Vice President, Deputy General Counsel* Terex Corporation

Michelle Deng Patent Counsel Genzyme Corporation

Jon Dudas *Partner* Foley & Lardner LLP

Catherine Sun *Partner* Foley & Lardner LLP

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Faculty Biographies

Bonita Lewis Bell

Bonita Lewis Bell is vice president, deputy general counsel at Terex Corporation based in Westport, CT. She is primarily responsible for leading the intellectual property function globally with a focus on short and long-term intellectual property strategy and portfolio management and advising on intellectual property related matters, including prosecution, enforcement and defense strategy, software licensing, and litigation. Additionally, Ms. Bell's team is responsible for supporting global information technology procurement and government programs.

Ms. Bell has extensive experience in intellectual property transaction, prosecution, and litigation, including work in government, private practice, and corporate settings. Prior to joining Terex, Ms. Bell was counsel at General Motors Corporation where she honed her transactional skills by focusing primarily on high value, complex telecommunication transactions; technology procurement and licensing; and intellectual property sharing transactions. Ms. Bell was also an associate in the litigation group at Crowell & Moring, where her practice focused on patent, trademark, copyright, trade secret, and antitrust litigation. Ms. Bell started her career as a patent examiner in the electrical arts at the U.S. Patent and Trademark Office, and during law school had the opportunity to serve as a student law clerk to the Hon. Randall R. Rader of the United States Court of Appeals for the Federal Circuit.

Ms. Bell received her BS from the University of Maryland and her JD from George Washington University Law School.

Michelle Deng

Michelle Deng is a patent attorney at Genzyme Corporation, in Framingham, MA, where she is responsible for patent and other IP matters for medical research and drug development.

For the past several years, Dr. Deng has worked extensively for clients in the life sciences and pharmaceutical industries. Her practice includes preparing and prosecuting U.S. and international patent applications; creating and maintaining strategic patent portfolios; preparing opinions on patent infringement, validity, and freedom to operate; as well as negotiating and drafting collaboration and license agreements. Prior to joining Genzyme, Dr. Deng was an associate in Goodwin | Procter LLP's litigation department and a member of its intellectual property group. Before entering the legal profession, she was a postdoctoral fellow at the Whitehead Institute for Biomedical Research, Massachusetts Institute of Technology. Dr. Deng is currently the secretary of the Chinese American IP Law Association (CAIPLA). She is a co-author of a recently published article on nature biotechnology entitled "Enforcing pharmaceutical and biotech patent rights in China" (November 2008).

Dr. Deng received her B.S. from Wuhan University in China, her Ph.D. degree from Arizona State University and J.D. degree from Suffolk University Law School.

Jonathan Dudas

Jonathan Dudas is a partner with Foley & Lardner LLP, in Washington, DC, where he works with the intellectual property and public affairs practices.

Mr. Dudas joined Foley as former under secretary of commerce for intellectual property and director of the United States Patent and Trademark Office. In this role, Mr. Dudas advised the President of the United States, the Secretary of Commerce, and the Administration about intellectual property matters and administered the laws of granting patents and trademarks and led the \$2 billion agency and its nearly 10,000 employees. As head of the world's leading intellectual property (IP) office, Mr. Dudas also developed and articulated administration positions on patent, copyright, and trademark issues, both domestic and foreign. As the nation's top IP official, Mr. Dudas led an unprecedented number of intellectual property cooperation and development missions throughout the world to improve IP systems and help innovators establish and enforce IP rights globally. Mr. Dudas led a dozen delegations to China on behalf of the United States. He negotiated and concluded US-China agreements with the leaders of the Patent Office (SIPO), the Trademark Office (CTO) and the Copyright Office (GAPP) in China. Mr. Dudas also served as counsel to the U.S. House Judiciary Subcommittee on Courts and Intellectual Property, and staff director and deputy general counsel for the House Judiciary Committee.

Mr. Dudas obtained his BS, summa cum laude, from the University of Illinois and his law degree from the University of Chicago, with honors.

Catherine Sun

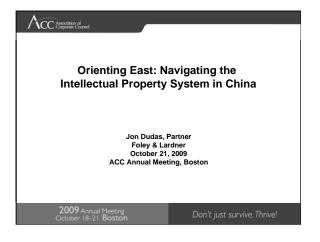
Catherine Sun is the managing partner of Foley & Lardner's Shanghai Office and chair of the firm's Asia practice. Ms. Sun is a member of the intellectual property litigation and international practices and the life sciences and entertainment and media industry teams. She works with the firm's clients on IP strategy, counseling and litigation, cross border mergers and acquisitions related IP, international technology transfer, licensing, and portfolio management.

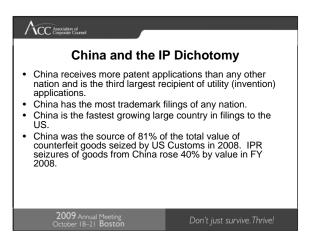
Prior to joining Foley, she was with the Shanghai office of an international law firm, where she was head of the China IP practice. Ms. Sun also spent time practicing law in the United States at a major national law firm, before returning first to Hong Kong and then to Shanghai to practice intellectual property law. Ms. Sun has also practiced intellectual property law in Beijing. While in the United States, Ms. Sun also was an in-

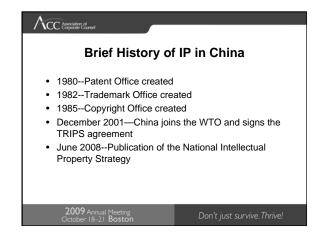
house attorney for a high-tech company working on the trans-Pacific interface and served as a student law clerk to the Hon. Randall R. Rader of the United States Court of Appeals for the Federal Circuit.

Ms. Sun is the author of numerous publications on IP-related transactions in China, and has lectured widely and participated in conferences on intellectual property law both in the United States and Asia.

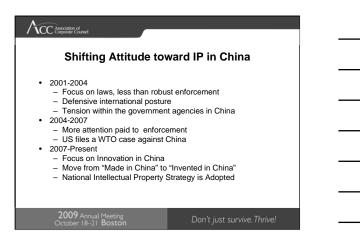
Ms. Sun received her LLB with honors from Peking University, and she earned her LLM degree from the George Washington University Law School.

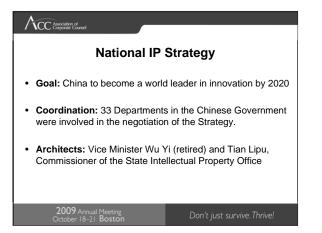






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Vis and International Cooperation IP is addressed at the highest political levels and working levels—President, Premier, Vice Premiers, Ministers, Vice Ministers and Directors—in diverse agencies October 2009—Memoranda of Understanding Signed between the USPTO and SIPO (patents), SAIC (trademarks) and GAPP (copyrights) China is a full participant of the IP5—5 largest patent offices in the world China is an observer in the Trademark Trilateral Meetings among the US, Japan and Europe

 Annual US-China Joint Commission on Commerce and Trade (Ministerial Level) progresses

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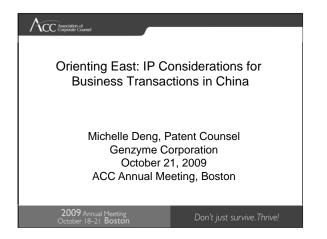






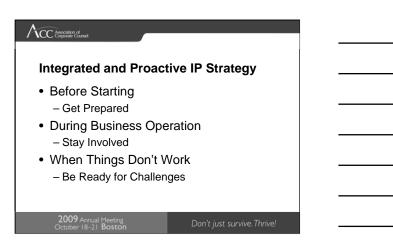
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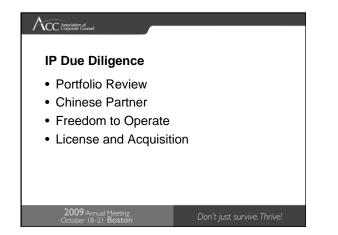
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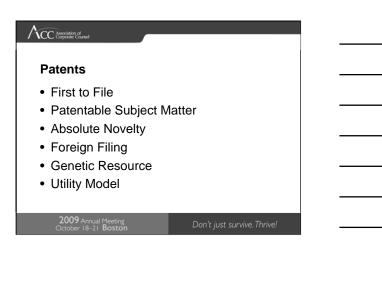
Be Prepared

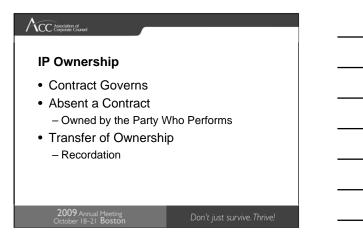
- Understand Different Forms of Available
 IP
- Be Aware of Key Differences and Requirements in China
- Evaluate Relevant Technology & Business
- Establish and Enforce IP Rights
- Conduct IP Due Diligence

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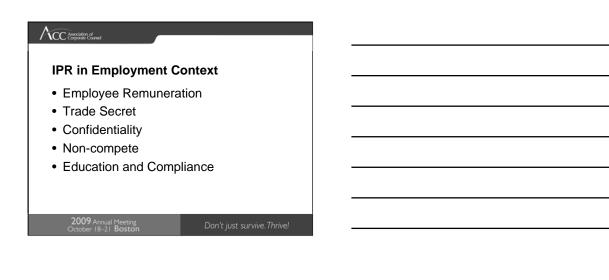
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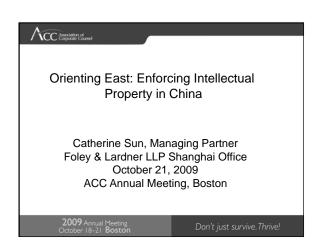












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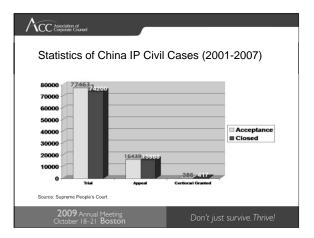
The Dynamics of the Intellectual Property (IP) Legislation in China

- Joined World Trade Organization in 1980

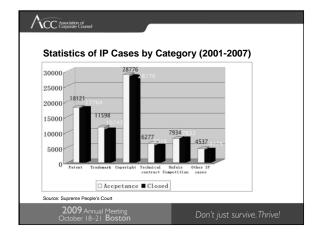
 Eight years of Accession
- PRC Trademark law took effect on March 1, 1983
- Third Amendment to the Patent Law effective on October 1, 2009
- Third Amendment to the Trademark Law is pending

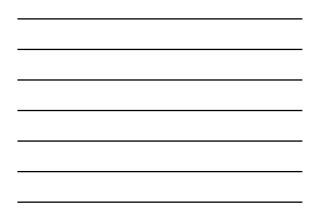
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Chint v. Schneider A Chinese Company Suing a French Company for Patent Infringement

- Forum shopping Wenzhou Intermediate Court as the trial court
- Patent at issue a Chinese utility model patent expired in November 2007
- Damages trial count rendered RMB 334
 million in damages
- In April 2009, case settled for RMB 157.5 million, the largest settlement in Chinese patent litigation history

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- Negotiation
- Mediation
- Arbitration
- Face saving (mianzi) still dictates resolution of disputes by non-court actions
- Administrative actions
- Civil actions
- Criminal actions
 Criminal actions mostly are applicable to trademark and copyright offenses
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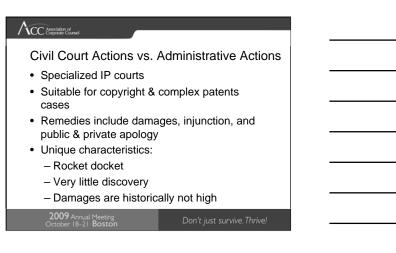
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Administrative Enforcement

- Agency for Industry and Commerce (AIC) and Technology Supervision Bureau (TSB)
- Suitable for trademark and simple design patent infringement only
- Quicker & Cheaper
- Evidence collection tool
- No damages

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Orienting East: IP in China Association of Corporate Counsel Annual Meeting October 21, 2009 Course Materials

- 1. Outline of The Chinese National Intellectual Property Strategy
- 2. "Third Amendment to the PRC Patent Law," Sharon Barner, Catherine Sun, & Yan Zhao (February 2009)
- 3. "PRC People's Supreme Court Patent Infringement Enforcement Guidance," Foley & Lardner LLP(July 2009)
- 4. "Patented in China: The Present and Future State of Innovation in China," Eve Y. Zhou, Ph.D., and Bob Stembridge, *Thomson Reuters Scientific* (2008)
- 5. "Enforcing pharmaceutical and biotech patent rights in China," Y. Philip Zhang and Michelle M. Deng, *Nature Biotechnology* (November 2008)
- 6. "Beat the first filing blues in China," Catherine Sun, *Managing Intellectual Property* (May 2008).
- "China 10-Point Patent Checklist: Integrating patents into an overall business strategy for a Western manufacturing entity in China;" Catherine Sun, Sharon Barner & Harold Wegner; *Journal of Commercial Biotechnology* (2009).

Outline of the Chinese National Intellectual Property Strategy¹ (Issued June 2008)

This Outline is formulated for the purpose of improving China's capacity to create, utilize, protect and administer intellectual property, making China an innovative country and attaining the goal of building a moderately prosperous society in all respects.

I. Preface

(1) Since the reform and opening up policy was introduced, China has maintained a sustainable and rapid economic and social development, and has made advances in science and technology and cultural creations, while the capacity for innovation has been constantly improved, and knowledge is playing an increasingly prominent role in China's economic and social development. China is now experiencing a new historical beginning, and it is of great strategic importance for the country to develop and utilize knowledge-based resources in order to transform the pattern of economic development, ease the constraints posed by demand for resources and environmental concerns, improve the nation's core competitiveness and meet the increasing material and cultural demands of the people.

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

(3) With years of development, China has been gradually improving its system of laws and regulations on intellectual property and constantly strengthening the enforcement level. Meanwhile, the intellectual property quantity has increased rapidly and their performance has constantly improved. Market entities have also made steady progress in improvement of their capacity to utilize intellectual property. China has expanded international exchanges in the field of intellectual property and increased its influence in international intellectual property affairs. The establishment and implementation of the intellectual property system have helped standardize China's market order, stimulated inventions and cultural creations, promoted China's opening up and importation of knowledge resources, and played an important role in China's economic and social development. However, China's intellectual property regime still needs improvement. The quality and quantity of the self-relied intellectual property still cannot meet the demands of economic and social development; the public awareness of the importance of intellectual

¹ This is a non-official translation to help people who do not understand Chinese to read China's National Intellectual Property Strategy Outline. In case of discrepancy between the original Chinese text and this translation, the Chinese text shall prevail.

Source: IPR in China (<u>www.ipr.gov.cn</u>); English (http://www.chinaipr.gov.cn/)

property is comparatively weak; the capacity of market entities to utilize intellectual property is not very strong; infringement of intellectual property is still a relatively serious problem; there are still some cases of abuse of intellectual property; the intellectual property service and support system and training for all types of intellectual property personnel lag behind its development; and the role of intellectual property in promoting economic and social development needs to be strengthened.

(4) Implementing the national intellectual property strategy to greatly promote China's capacity in creation, utilization, protection and administration of intellectual property will help improve China's capacity for independent innovation and aid in efforts to make China an innovative country. It will also be conducive to improving China's socialist market economy, standardizing market order and encourage the society to be more creditworthy. It will also increase the market competitiveness of Chinese enterprises and strengthen the core competitiveness of the country. Finally, it will facilitate China's opening up further to the outside world, thereby leading to a win-win situation between China and the rest of the world. We must implement this intellectual property strategy an important national strategy and we must step up efforts in the area of intellectual property.

II. Guiding Principles and Strategic Goals

1. Guiding Principles

(5) In implementing the national intellectual property strategy, we need to follow the guidance of Deng Xiaoping Theory and the important thought of "Three Represents", comprehensively apply the Scientific Outlook on Development and abide by the policy of encouraging creation, effective application, legal protection and scientific administration. We must concentrate our efforts to improve the intellectual property system, actively work to create a favorable legal environment, market environment and cultural environment for the development of intellectual property in order to greatly improve China's capacity to create, utilize, protect and administer intellectual property. This will provide strong support for the effort to make China an innovative country and develop a moderately prosperous society in all respects.

2. Strategic Goals

(6) By 2020, China will become a country with a comparatively high level in terms of the creation, utilization, protection and administration of IPRs. The legal environment for IPRs is much better, market entities are much better at the creation, utilization, protection and administration of IPRs, the public awareness of intellectual property is increased greatly, the quality and quantity of the self-relied intellectual property are able to effectively support the effort to make China an innovative country, the role of the intellectual property system in promoting economic development, the culture prosperity and social progress in China become very apparent.

(7) Goals for the next five years:

- The level of the self-relied intellectual property will be higher by a large margin and the quantity of intellectual property will be greater. China will rank among the advanced countries of the world in terms of the annual number of patents for inventions granted to the domestic applicants, while the number of overseas patent applications filed by Chinese applicants should greatly increase. A number of world-famous brands will emerge. The proportion of the GDP accounted for by the value of core copyright industries will greatly increase. China should own the rights to a number of high-quality new varieties of plants and high-level layout-designs of integrated circuits. Trade secrets, geographical indications, genetic resources, traditional knowledge as well as folklores will be effectively protected and reasonably utilized.

- The benefits of utilizing intellectual property rights (IPRs) will be increased significantly and the

proportion of products rich in IPRs should grow significantly. Enterprises should make progress in improving their system for managing intellectual property, invest more in the area of intellectual property and significantly improve their capacity to utilize intellectual property in market competition. A number of preponderant enterprises with famous brands, core intellectual property and rich experience in utilizing the intellectual property system will emerge.

- The protection of IPRs will be significantly improved. Infringement of IPRs, such as piracy and counterfeiting, should be significantly reduced, the expense of protecting intellectual property right will decrease a great deal and abuse of intellectual property should be effectively curbed.

- The awareness of the IPRs in society, especially among market entities, will be greatly enhanced and a favorable intellectual property culture should be formed.

III. Strategic Focuses

1. Improving the Intellectual Property Regime

(8) Laws and regulations concerning IPRs need to be improved. Special intellectual property laws, such as the Patent Law, Trademark Law and Copyright Law, and related regulations need to be promptly revised. Legislation concerning genetic resources, traditional knowledge, folklores and geographical indications should be formulated as needed. The uniformity and coordination of intellectual property legislation need to be strengthened to improve the practicability of laws and regulations. Intellectual property-related provisions contained in laws and regulations concerning unfair competition, foreign trade, science and technology and national defense need to be improved.

(9) The intellectual property law enforcement and administration systems need to be strengthened. The judicial protection and administrative law-enforcement systems need to be strengthened, while judicial protection of IPRs should play its leading role. The efficiency and level of law-enforcement need to be improved and public services need to be strengthened. The reform of the intellectual property administration system needs to be continued to establish a system that matches powers with responsibilities, divides work in a rational way, fosters scientific decision-making and ensures smooth enforcement and effective supervision.

(10) The guiding role of intellectual property in economic, cultural and public policies needs to be strengthened. More efforts need to be adopted to improve coordination between intellectual property policy and the policies of industry, region, science and technology and trade. Intellectual property policy suitable for the development of relevant industries needs to be formulated to promote adjustment and optimization of industrial structures. Measures need to be taken in line with the different features of regional development to improve intellectual property support policy and foster economies suitable to the region and thus promote balanced regional economic development. Establish intellectual property working mechanism for important scientific and technological projects to provide comprehensive services throughout the process with the focus on the acquisition and protection of intellectual property. Intellectual property policy related to foreign trade needs to be improved. The mechanisms for administering intellectual property, early warning and emergency response, overseas IPRs protection and dispute settlement need to be established and strengthened in foreign trade sector. Coordination and uniformity between intellectual property policy and policies of culture, education, science and health need to be strengthened to safeguard the right of the public to legally and rationally utilize innovation findings and information in their cultural, educational, scientific and public health activities, promote the fair sharing of innovation and information, and ensure that the government is able to deal with public crises.

2. Promoting the Creation and Utilization of Intellectual Property

(11) We need to guide and support market entities to create and utilize intellectual property through the use of policies related to finance, investment, government procurement, industrial development, energy and environmental protection. The guiding role of intellectual property policies in scientific innovation activities needs to be strengthened. Technological innovation will take legal industrialization as the basic precondition, and make the acquisition of IPRs as its goal, with being accepted by the technical standards as its endeavor direction. The right ownership and benefit sharing mechanisms for scientific and technological inventions made as part of state-supported projects need to be improved. Indicators of IPRs need to be included into the systems for assessing the implementation of scientific and technological plans and the performance of state-owned enterprises. Raise the proportion of exportation of the goods rich in intellectual property step by step. Promote fundamental changes in the trade growth pattern and optimize trade structure.

(12) We need to encourage enterprises to be the principal entity in the creation and utilization of intellectual property. Independent innovation is encouraged to acquire IPRs and be commercialized and industrialized, and enterprises are guided to realize the market value of their IPRs through rights transferring, licensing, pledging or other means. Higher education institutions and scientific research institutes need to be encouraged to play important roles in the creation of intellectual property. Choose some important technological areas to create a number of core self-relied intellectual properties and technical standards. Encourage the public to take part in innovations and cultural creations. Promote the creation of excellent cultural products.

3. Strengthening the Protection of IPRs

(13) Revise laws and regulations to punish infringements on IPRs and strengthen judicial punishment. Help right holders to improve consciousness and capacity to protect their own interests. Lower the cost of right enforcement. Increase the cost of infringements. Curb infringements effectively.

4. Preventing Abuses of IPRs

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

5. Fostering a Culture of IPRs

(15) Strengthen the knowledge propagation on intellectual property right and increase the awareness of intellectual property right in the whole society. Carry out the ordinary intellectual property right education extensively. Increase the intellectual property right content in the national promotion of the public moral culture and the national ordinary education in law. By advocating the moral concepts of being proud of innovation and honesty and ashamed of plagiarism and counterfeiting or cheating, the intellectual property right culture could be established throughout China, characterized by respect for knowledge, enthusiasm for innovation and creation, being honest and obeying law.

IV. Specific Tasks

1. Patent

(16) Make advanced development plans according to the nation's strategic needs in some sectors such as biology, medicine, information, new materials, advanced manufacturing, new energy, oceanography, resources, environmental protection, modern agriculture, modern transportation, aeronautics and

property is comparatively weak; the capacity of market entities to utilize intellectual property is not very strong; infringement of intellectual property is still a relatively serious problem; there are still some cases of abuse of intellectual property; the intellectual property service and support system and training for all types of intellectual property personnel lag behind its development; and the role of intellectual property in promoting economic and social development needs to be strengthened.

(4) Implementing the national intellectual property strategy to greatly promote China's capacity in creation, utilization, protection and administration of intellectual property will help improve China's capacity for independent innovation and aid in efforts to make China an innovative country. It will also be conducive to improving China's socialist market economy, standardizing market order and encourage the society to be more creditworthy. It will also increase the market competitiveness of Chinese enterprises and strengthen the core competitiveness of the country. Finally, it will facilitate China's opening up further to the outside world, thereby leading to a win-win situation between China and the rest of the world. We must implement this intellectual property strategy an important national strategy and we must step up efforts in the area of intellectual property.

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- The benefits of utilizing intellectual property rights (IPRs) will be increased significantly and the

the ways of copyright utilization and reduce the costs and risks involved in copyright transactions. The roles of copyright collective administration organizations, industrial associations, agencies and other intermediary organizations need to be brought into full play in the process of commercializing copyrights.

(27) Deal with piracy according to law. Intensify the punishment against piracy, focusing on curbing the large-scale production, selling and dissemination of pirated products to effectively reduce copyright piracy.

(28) Adopt effective measures to address challenges brought about to copyright protection by the development of the Internet and other new technologies. Properly balance the need for copyright protection and the need for information dissemination. We must protect copyrights in accordance with law while at the same time promoting the dissemination of information.

4. Trade secret

(29) Guide market entities in establishing a trade secret management system in accordance with law. The behavior of stealing trade secret should be severely punished in accordance with law. Properly balance the need for protecting trade secret and the freedom to choose employment and balance non-competition undertaken by insiders and the need for normal personnel flow to safeguard employees' lawful rights and interests.

5. New Varieties of Plants

(30) Establish an incentive mechanism to support the cultivation of new varieties of plants and to facilitate the transformation of innovation findings in breeding into new plant variety rights. A number of breeding bases holding rights in new varieties of plants need to be established. Technology support systems related to new varieties of plants needs to be set up and improved. The work of formulating the guidelines for the conduct of tests of new varieties of plants needs to be expedited. The examination and testing level needs to be raised.

(31) Make the balance of interests among resource suppliers, breeders, producers and business operators more rational, with the emphasis on the protection of lawful rights and interests of farmers. Strengthen the awareness of the need to protect the new plant variety rights among breeding bases and farmers to ensure that the variety rights owners, producers and sellers of new varieties and farmers are all benefited.

6. Intellectual Property in Specific Areas

(32) Improve the protection system for geographical indications. A system of technical standards, a quality guarantee system and an examination system for geographical indications need to be established and strengthened. Carry out a thorough survey of geographical indication resources and give support to products of geographical indications. Promote the transformation of natural and humanistic advantages with regional characteristics into practical productivity.

(33) Strengthen the protection, development and utilization systems for genetic resources to prevent loss and inappropriate use of them. Balance interests between the need to protect genetic resources and the need to develop and utilize them, and to develop a reasonable mechanism for genetic resource access and benefit sharing. We must guarantee the right of prior-informed consent enjoyed by suppliers of genetic resources.

(34) Establish a sound protection system for traditional knowledge. Support the collation and passing down of traditional knowledge to further its development. A coordination mechanism for administration,

protection and utilization of IPRs for traditional medicine needs to be improved and the protection, development and utilization of traditional arts need to be strengthened.

(35) Strengthen the protection of folklores and to promote their development. Extensively gather folklores and set up a benefit sharing mechanism that will assure a reasonable balance between conservators of folklores and those who use those resources to create new works, in order to protect the lawful rights and interests of individuals and communities.

(36) Make the utilization of exclusive rights for layout-designs of integrated circuits more effective and thus promote the development of the integrated circuit industry.

7. IPRs Related to National Defense

(37) Establish a unified coordination and administration mechanism for intellectual property related to national defense, particularly focusing on the resolution of major issues such as ownership and benefit distribution, compensation for use, incentive mechanism and effective exploitation of technologies in emergencies.

(38) Improve the administration of intellectual property related to national defense. The administration of intellectual property needs to cover all links in national defense, including research, production, operation, equipment procurement and guarantee, and project management, and control of major intellectual property related to national defense should be strengthened. A guideline to key technologies needs to be published. Create a number of the self-relied intellectual property in areas such as key technologies for weapons and military equipment and high technologies for both military and civilian purposes. An early warning mechanism for intellectual property related to national defense needs to be established, and special examinations of IPRs related to national defense should be carried out in military technology cooperation and arms trade.

(39) Make more effective use of intellectual property related to national defense. The rules for keeping secrecy and declassification of intellectual property related to national defense need to be further improved. Promote the use of intellectual property related to national defense for civilian purposes with the condition that national security and the interests of national defense are not compromised. Encourage the use of intellectual property for civilian purposes in the area of national defense.

V. Strategic Measures

1. Increasing the Capacity to Create Intellectual Property

(40) Establish a market-oriented system for the creation of self-relied intellectual property with enterprises as the backbone of the system and manufacturers, universities and research institutes as close cooperation partners. Enterprises need to be guided to search intellectual property information before starting their own research and development projects or business operations. Enterprises need also be supported in their efforts to form the self-relied intellectual property and strengthen their capacity to transform innovations into intellectual property through original innovation, joint innovation and secondary innovation based on imported technologies. Enterprises as well as other market entities should also be encouraged to obtain intellectual property overseas. Enterprises need to be guided to change the way they compete, improve technological innovation, raise the quality of their products and services and create their own well-known brands.

2. Encouraging the Commercialization and Utilization of IPRs

(41) Guide more innovative elements towards enterprises, support the commercialization of innovations made by high education institutions and research institutes to enterprises, stimulate the application and industrialization of intellectual property in enterprises, and shorten the time for applying it in industrial production. We need to launch various kinds of pilot or demonstration projects for intellectual property, and to improve the overall capacity to utilize intellectual property and handle competition in intellectual property.

(42) Encourage and support market entities to improve their management systems for technological data and trade secrets, and to establish a value assessment, a statistics and an accounting system for intellectual property. They are also encouraged to work out an information search system for intellectual property and an early-warning system for major events, and improve the system for administration of intellectual property in foreign cooperation.

(43) Encourage market entities to actively respond to intellectual property infringements and lawsuits in accordance with law, and to improve their capacity for handling intellectual property disputes.

3. Expediting the Development of the Legal System for Intellectual Property

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

4. Improving Intellectual Property Law Enforcement

(45) Improve the trial system for intellectual property, optimize the allocation of judicial resources and simplify remedy procedures. Studies need to be carried out on establishing special tribunals to handle civil, administrative or criminal cases involving intellectual property. Studies also need to be done to reasonably centralize jurisdiction over cases involving patents or other cases of a highly technical nature. Explore issues on setting up courts of appeal for cases involving intellectual property. Judicial organs for handling cases involving intellectual property need to be further strengthened and well-staffed to improve the handling of cases and enforcement of the law.

(46) Judicial interpretation on intellectual property needs to be improved. Cases involving intellectual property require more professional knowledge, and therefore a sound litigation system needs to be established that includes judicial authentication, expert witnesses and technical investigation, and the system of provisional measures prior to action involving intellectual property needs to be improved. Procedures for determining and granting patent or trademark rights need to be reformed, and studies need to be conducted on transforming bodies that hear patent invalidation and trademark review and adjudication cases to quasi-judicial organs.

(47) Improve the overall competence of intellectual property law-enforcement personnel and reasonably distribute law-enforcement resources to improve the efficiency of law enforcement. Special, well-planned and focused actions for the protection of intellectual property should be launched in cases of repeated intellectual property infringements, organized intellectual property infringements and large-scale counterfeiting and piracies. Administrative law-enforcement departments need to speed up the referral of criminal cases involving intellectual property to judicial organs, and judicial organs should make greater

efforts to receive criminal cases involving intellectual property.

(48) Customs law enforcement and border protection of intellectual property need to be strengthened to maintain order in import and export and improve the reputation of China's export commodities. International cooperation in customs law enforcement needs to be fully utilized in order to effectively crack down on cross-border illegal acts and crimes involving intellectual property. Customs need to have influence on international intellectual property protection.

5. Strengthening the Administration of Intellectual Property

(49) Formulate and implement regional and industrial strategies on intellectual property. A mechanism for reviewing intellectual property for important economic events needs to be established and strengthened. Projects for creation and industrialization of the self-relied intellectual property need to be supported as they meet the demand of economic and social development.

(50) More human resources are needed to administer intellectual property, professional training needs to be enhanced so as to raise the competence of personnel needs. People's governments at or above the county level may establish intellectual property administration departments in line with their respective economic and social development.

(51) The systems for examination and registration of intellectual property need to be improved to increase capacity building, optimize procedures, improve efficiency, reduce administrative cost and upgrade the level of public services involving intellectual property.

(52) Develop a national public service platform for basic information on intellectual property. Highquality databases of basic intellectual property information should be developed that include patents, trademarks, copyrights, layout-designs of integrated circuits, new varieties of plants and geographical indications. Accelerate the development of a common search system suitable for Chinese search practices. Agencies to test and preserve new varieties of plants need to be improved. An information platform for intellectual property related to national defense needs to be established. Guide and support the development of intellectual property information databases in various regions and sectors that meet their own needs. Intellectual property system and resource integration and information sharing need to be promoted.

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

6. Developing Intermediary Services for IPRs

(54) Improve the administration of intellectual property intermediary services, make it a self-regulated industry, and establish a system for monitoring such services, including credit information management, reputation assessment and punishment recording. The practice for IPRs appraisal needs to be further regulated to increase its credibility.

(55) Establish a professional training system for intellectual property intermediary services, improve vocational training in intermediary services and standardize the administration of professional qualifications. The scope of services for an intellectual property agent and other employees in intermediary services needs to be clearly defined and studies on general lawyers acting as intellectual

property agent need to be conducted. An intermediary service system for intellectual property related to national defense needs to be improved. Great efforts need to be made to improve the capacity of intermediary services to handle international applications for intellectual property, settle disputes and participate in international intellectual property affairs.

(56) Strengthen the role of industrial associations and support their intellectual property work, promote intellectual property information exchange and organize a joint effort to enforce IPRs. The government should strengthen its supervision and guidance in the intellectual property work of industrial associations.

(57) The role of the technology market needs to be strengthened and an intellectual property trading system needs to be established, which provides sufficient information, allows active trading and has an orderly environment. Trading procedures need to be simplified; the cost of trading needs to be reduced and services need to be improved.

(58) Develop commercial intellectual property information services to meet the demands of all relevant parties for intellectual property information. All sectors of society are encouraged to invest in the development of intellectual property information and enterprises are encouraged to participate in the development and utilization of intellectual property information with potential added value.

7. Developing Intellectual Property Human Resources

(59) Establish an interdepartmental coordination mechanism and make overall plans for the development of intellectual property human resources. Establishment of national and provincial intellectual property expert databases and professional information networks needs to be accelerated.

(60) Set up national education bases to train intellectual property professionals. The training of senior intellectual property tutors needs to be accelerated. A sub-discipline program on intellectual property should be set up and the higher education institutions which meet the requirements are supported to establish programs for conferring intellectual property master's and doctor's degrees. Large-scale training programs need to be organized to train all types of intellectual property professionals, focusing on training of urgently needed management personnel and personnel to provide intermediary services involving intellectual property.

(61) Work out training plans to provide comprehensive training on intellectual property to Party and government leaders, civil servants, managers of enterprises and institutions, technical and professional staff, writers and artists, and teachers.

(62) Improve relevant systems for attracting, exploiting and managing intellectual property professionals, improve the human resources structure and encourage reasonable mobility of personnel. In view of the implementation of the Civil Servant Law, we need to improve the civil servant administration system in intellectual property administration departments. A professional and technical assessment system for intellectual property professionals needs to be established in accordance with the overall requirements of the reform to the professional titles system of the State.

8. Promoting the Cultivation of an Intellectual Property Culture

(63) Set up a working mechanism for publicizing information about intellectual property that is led by the government and supported by the media, in which the public widely participates. The coordination mechanism needs to be improved and relevant policies and working plans need to be formulated to promote public awareness of intellectual property and the development of an intellectual property culture.

(64) Offer intellectual property courses in higher education institutions and to introduce education on intellectual property into the quality-based education to students of such institutions. A general education plan on intellectual property needs to be formulated and implemented, and intellectual property education needs to be listed into teaching plans in primary and high schools in whole China.

9. Expanding International Exchanges and Cooperation in Intellectual Property

(65) Strengthen international exchanges and cooperation in the field of intellectual property. An international information exchange mechanism for intellectual property needs to be established and strengthened. International and regional cooperation needs to be strengthened in the development and utilization of intellectual property information resources and infrastructure. Encourage international cooperation on training of intellectual property professionals. Students studying overseas under State-financed projects are guided to pursue programs related to intellectual property, whereas those funded otherwise are encouraged to do so. Highly talented intellectual property professionals should be introduced from overseas and employed in China. China needs to actively participate in the development of international intellectual property order and effectively involve itself in undertakings of international organizations.

(Issued by the State Council of the People's Republic of China on June 5, 2008)



FEBRUARY 2009

Third Amendment to PRC Patent Law

On December 27, 2008, the Standing Committee of the National People's Congress (NPC) of the People's Republic of China (PRC) adopted the third amendment to the current Patent Laws (<u>http://www.lawinfochina.com/law/display.asp?db=1&id=7289</u>), which already had been revised in 1992 and again in 2000. The amended PRC Patent Law (New Patent Law) will go into effect on October 1, 2009. The corresponding Implementing Regulations, which primarily address procedural specificities, also are currently under revision, and we expect that the amended regulations will be published and implemented concurrently.

Previously in *Legal News Alert: China*, (September 25, 2008) (<u>http://www.foley.com/publications/pub_detail.aspx?pubid=5279</u>), we reported the submission of a draft amendment (August 2008 Version) to the Standing Committee of the NPC, and discussed certain important issues. As compared to the August 2008 Version, the New Patent Law mainly differs on two issues: the first filing requirement and patent infringement exemptions.

1. Patentability Standard Raised

The current Patent Law employs a "modified" novelty standard in the determination of the prior art for assessing the novelty and inventiveness of a utility patent and the novelty of a design patent — that is, prior public use such as sales, offer for sales, and manufacturing outside China would have no impact on the assessment of a Chinese patent. On the contrary, the New Patent Law has adopted an absolute novelty standard such that any prior public disclosure anywhere in the world, including public use, can be cited as a prior art reference against the novelty or inventiveness of a Chinese utility patent application or the novelty of a design patent application. The New Patent Law also has raised the novelty requirement for design patents by requiring that the design be substantially different from existing designs and from the combinations of existing design characteristics.

2. First Filing Requirement Replaced by National Security Review

The current Patent Law requires that an invention-creation made in China by a Chinese individual or entity be filed first in China. In practice, this first filing requirement is often circumvented by transferring the invention to a foreign entity, especially a foreign affiliate company, which is not obliged to obey the first filing requirement.

The New Patent Law has now replaced the first filing requirement with a national security review by the State Intellectual Property Office (SIPO) prior to the filing in any foreign country; failure to do so will result in a refusal to grant the corresponding patent in China, if ever filed. Since the review requirement is based on the place of invention, irrespective of the nationality or residency of the applicant, the possible circumvention of the current first filing requirement would not be applicable after the implementation of the New Patent Law.

The proposed amendments to the Implementing Regulations of the Patent Law (Draft Implementing Regulations), which are currently being reviewed by the SIPO and are expected to become effective together with the New Patent Law, have set forth details about this national security review requirement.

Specifically, under the Draft Implementing Regulations, the applicant seeking first filing in a foreign country shall provide a detailed description of the invention together with the filing of a request for national security review. The SIPO is required (1) to inform the applicant within two months upon the filing of the request if it believes that a national security review is necessary and (2) to decide within four months whether the invention relates to national security such that it shall be kept confidential. If within two- or four-month statutory period the SIPO has not responded, the favorable decisions are assumed, and the applicant is free to file a patent application in a foreign country first.

Furthermore, under the Draft Implementing Regulations, the filing of a PRC patent application is tantamount to filing a request for a national security review in respect of possible subsequent filings in foreign countries, which is similar to the practice in many foreign jurisdictions. This appears to imply that the applicant will have to wait two to four months to clear the national security review process before any subsequent foreign filings.

3. Protections for Design Patents Broadened

The New Patent Law extends the protections for design patents to cover the activities of offering for sales so that such offer-for-sale activities are prohibited without the design patentee's authorization.

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4. Possible Damages for Patent Infringement Increased

The New Patent Law explicitly states that the damages for patent infringement shall include the reasonable expense incurred by the patent owner for stopping the infringement. It also has increased the maximum statutory damages from RMB 500,000 to RMB 1,000,000 with the intent of strengthening the patent protections.

5. Patent Co-Owners' Rights Better Defined

The current Patent Law fails to stipulate whether and how a patent co-owner can individually exploit co-owned patent(s). The New Patent Law explicitly provides that, given a lack of a mutual agreement between the co-owners, each co-owner can implement the co-owned patent(s) by himself. Each co-owner also can grant a non-exclusive license to a third party to use such patent(s) on the condition that the license fees are shared with the other co-owner(s).

Under the New Patent Law, however, consensus among the co-owners is required to exploit the co-owned patent(s) in circumstances other than the aforementioned; the requirement appears to apply to the patent enforcement as well. If that is the case, such a requirement may adversely impact the effectiveness of enforcing a co-owned patent. Therefore, under the New Patent Law, it would be prudent to avoid joint ownership if at all possible.

6. Prior Art Defense Codified

Under the current Patent Law, in a patent infringement case, the defendant needs to file an invalidation petition with the Patent Re-Examination Board in order to challenge the patent at issue, and the patent infringement and invalidation proceedings run parallel to each other. Very often, such a parallel system inevitably prolongs the court proceeding, which may not be beneficial to the alleged infringer, especially if the accused infringing product or method actually falls within a piece of prior art. The New Patent Law seeks to simplify certain infringement proceedings by codifying the doctrine of prior art defense, which has already been adopted by the People's Courts in practice. Under this doctrine, the People's Court may find no infringement if the defendant has evidence to prove that his technology or design is covered by or performed in accordance with a piece of prior art or prior art design. It is not clear whether the defendant also may rely upon a combination of prior art (or designs). We expect to see further clarification by the judicial bodies.

7. Patent Infringement Exemptions Expanded

The New Patent Law has expanded patent infringement exemptions to cover parallel importation and to introduce an exemption, similar to the Bolar exemption available in the United States, to allow production, use, and importation of patented pharmaceutical products or medical equipment for administrative approval purpose.

Readers may recall that the August 2008 Version only explicitly exempted from patent infringement the manufacturing of drugs or medical equipment for administrative approval purpose, but noticeably not the use or importation of the drugs or medical equipment, as the PRC government had been quite indecisive in this issue.

With a rather "complete" Bolar exemption now introduced in the New Patent Law, more clarifications are provided in respect of the legitimacy of clinical trials in which the drugs or medical equipment would have to be used and tested.

8. Other Amendments in Accordance With Certain Recently Joined International Treaties

Firstly, the New Patent Law proposes to preserve in the current Patent Law certain provisions of the Doha Declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public Health of 2001 and the World Trade Organization (WTO) Decision of 2003 on the Doha Declaration with respect to compulsory licensing. Specifically, under the New Patent Law, the SIPO may, for public health purposes, grant compulsory license(s) to third parties to manufacture patented drugs and to export the drugs to (1) a least developed country or (2) a WTO member that has no or insufficient capacity to produce the patented drugs and that has fulfilled the relevant procedures in accordance with the relevant WTO treaties.

Secondly, in light of the relevant TRIPS provisions, the New Patent Law provides that, where it is determined through a judicial or administrative procedure that a patentee's exercise of his patent right is an act intended to eliminate or restrict competition, the SIPO may grant a compulsory license upon request.

In addition, in light of the Convention on Biological Diversity, the New Patent Law requires that for an invention-creation, the completion of which depends upon certain genetic resources, the applicant shall disclose the direct source and the original source of such genetic resources, aiming to prevent illegal theft of China's genetic resources.

Conclusion

Unlike the first two rounds of revisions to the Patent Law, China voluntarily initiated the third amendment as part of the implementation of the National Intellectual Property Strategy. The legislative purposes are mainly to encourage innovation and improve China's international competitiveness. Therefore, the New Patent Law appears to have drawn carefully a balance between the interests of the patent holders and the public by providing greater certainty in terms of patentability and enforcement. With the implementation of the New Patent Law, we expect to see improved patent protections in China.

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PRC People's Supreme Court Patent Infringement Enforcement Draft Guidance Foley & Lardner LLP (July 2009)

PRC Supreme People's Court (SPC) Justice He Zhong introduced the draft of Several Provisions of the Supreme People's Court on Issues Concerning Applicable Laws to the Trial of Patent Infringement Controversies (Judicial Interpretations). The Judicial Interpretations draw from and parallel the implementation of the recent Third Amendment to the Patent Law.

The Judicial Interpretations document is particularly important, as it comes from the SPC and, when finalized, will represent a powerful interpretative tool for Chinese patent law and practice concerning issues such as claim construction, standards for determining patent infringement, and calculation of damages.

Scope of Patent Protection

1. Level of Skill in the Art

Specifically, the Judicial Interpretations document sets forth that the scope of protection is determined by how one possessing ordinary skill in the art would construct the claims in light of the specification and drawings (Section 2).

2. Equivalents

The scope of claim protection also shall include technologies that substantially use the same means to implement substantially the same functions and to achieve substantially the same goals, and that can be perceived by one possessing ordinary skill in the art without creative work at the time of infringement (Section 4).

3. Design Patent Infringement

For design patents, identicalness or similarity of designs shall be determined in accordance with the knowledge and cognition of the "relevant public." The term "relevant public" is defined as a person who has general knowledge of the concerned patented design; who has a certain capacity of distinguishing shapes, patterns, or colors of different designs; and who does not usually notice trivial variances in the shapes, patterns, or colors (Section 11).

4. Narrow Interpretation for "Means" Claims

The Judicial Interpretations document also provides for narrow interpretation of means-plus-function claims, similar to the United States (35 USC §112, \P 6).

However, during prosecution, most patent examiners currently read the means-plus-function claims broadly to cover all possible mechanisms that perform the same function. Such examination practice is likely to change in light of the Judicial Interpretations.

5. All Elements Rule

The Judicial Interpretations document also explicitly requires that all technical features or their equivalents shall be present in the accused infringing product for a finding of patent infringement (Section 8). This essentially abandons the widely criticized "superfluity establishing principle," which was adopted by the Beijing High People's Court in an earlier decision. In that decision, the Court considered a feature of an independent claim apparently "non-essential" and removed it from consideration when determining infringement.

6. Prosecution History Estoppel (Narrowing Amendments)

The Judicial Interpretations document indicates that, if during prosecution or invalidity proceedings, a patent applicant or patent holder abandoned or narrowed the scope of certain claims, the scope of protection shall exclude such abandoned subject matter (Section 7).

Prior Art Defense

The Third Amendment to the Patent Law codifies the doctrine of prior art defense, under which the SPC may find no infringement if the defendant has evidence to prove that his technology or design is covered by or performed in accordance with prior art or prior art design. The Judicial Interpretations document requires the reliance upon one piece of prior art (or design) in such a defense, but also allows certain changes from the cited prior art. For example, with respect to invention or utility model patents, the features of the accused infringing product can be "equivalents" to those of the prior art; with respect to design patent, the design of the accused infringing product can be "similar" to that of the prior art.

Cease and Desist Letters

The Judicial Interpretations document sets forth that the accused infringer is entitled to file a declaratory judgment if the patentee — within one month after receipt of written notice from the accused infringer who has received a cease and desist letter therefrom, urging the patentee to take legal actions — fails to withdraw this letter or to bring a lawsuit. Such an additional procedural requirement may give the patentee significant advantages over the accused infringer in terms of forum shopping.

PATENTED IN CHINA

THE PRESENT AND FUTURE STATE OF INNOVATION IN CHINA

BY EVE Y. ZHOU, PH.D., AND BOB STEMBRIDGE

SCIENTIFIC



CHINA'S ECONOMY HAS SHIFTED FOCUS,

MOVING AWAY FROM TRADITIONAL AGRICULTURE AND MANUFACTURING TOWARD INNOVATION-ORIENTED ACTIVITIES.

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INTRODUCTION

The 2008 Beijing Olympic Games had, as a stunning backdrop, China, whose meteoric growth has attracted attention and curiosity from around the world. As the increasing wealth of the population and improved standards of living offer visible signs of the country's development, major changes have also gone on behind the scenes. China's economy has shifted focus, moving away from traditional agriculture and manufacturing toward innovation-oriented activities. Since the Chinese economic reform started in 1978, China has emerged from a poor developing country to become the second-largest economy in the world after the United States (U.S.)¹

More recently, the Chinese government has encouraged the country to embrace innovation through a variety of measures. It has increased the overall research and development budget for the country, introduced tax breaks and monetary incentives to increase indigenous innovation and continued investing in the nation's academic institutions, which have become a driving force behind Chinese patenting.

In just 20 years after the country's Patent Law took effect in 1985, China has become the third-largest patent office in the world by annual invention patent applications, after the U.S. and Japan. From 2003 to 2007, China's GDP grew at an average annual rate of 9.75% while Chinese invention patent applications grew at an average of 34.36% per year. If current trends continue, China is set to dominate the patent information landscape in the not-too-distant future.

This report takes a look at current patent trends and speculates about how the world of patent information will look in five years. The driving factors for China's patent boom are analyzed using data drawn from Thomson Reuters. Patent volumes and trends are explored, as well as the underlying causes of increased innovation in China, including economic and government policy factors.

1 The World Fact book, United States Central Intelligence Agency (CIA), March 20, 2008.

PAST PERFORMANCE

The patent offices of the U.S., Japan, Europe (EPO), Republic of Korea and China account for 75% of all patents filed and 74% of patents granted worldwide.² An analysis of patent volumes over the last five years from these five major offices shows that inventions from China have been growing at a faster rate than any other region.

There are several attributes that can be measured to identify and track innovation trends in a particular region:

- **Total volume of patents.** This gives a measure of the total patenting activity in a region that involves two aspects those inventions patented first in a region (basics) and those other inventions for which protection is sought in order to manufacture, use or sell the invention or products in the region (equivalents).
- **The basic patent volume.** This gives a clearer measure of home-grown innovation by providing a measure of how many inventions are patented first in the region.
- **The ratio of basics to total volume.** This is a broad indication of inventiveness of a region compared to how attractive it is perceived to be as a market by both home-grown and external industry.

Using data from the Thomson Reuters value-added patent collection Derwent World Patents Index (DWPI), the trends in patenting according to the above measures are compared for the U.S., Japan, Europe (EPO), Republic of Korea and China.

^{2 &}quot;WIPO Report Shows Internationalization of Patent Trends", World Intellectual Property Office, Press Release 463 Geneva, October 16, 2006.

TOTAL PATENT VOLUMES 2001 - 2007

Exhibits 1 and 2 show the five patent offices' total patenting volume annually from 2001 to 2007 and in aggregate during the same period. Japan has the highest total patent volumes year to year during the period, but its lead narrows as the U.S. catches up.³ Europe and Korea have similar volumes and growth trends. The striking difference among these regions is China – from humble beginnings, it is experiencing the most rapid growth and has surpassed Europe and Korea since 2005. In aggregate, China, Korea and Europe are on par with one another, each accounting for 12% of the group's total.

3 The large growth in volume of US patents from 2001-2002 may be explained by a change in US law at this time, allowing publication of patent applications 18 months after filing where previously publication only occurred on grant of a patent. Only a proportion of applications proceed to grant – those that were not granted would hitherto have been invisible.

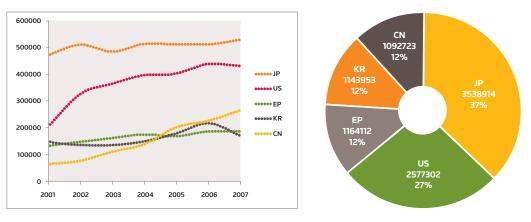
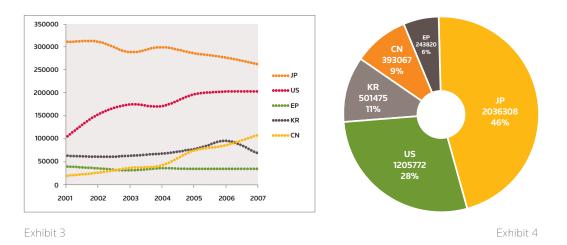


Exhibit 1

Exhibit 2

BASIC PATENT VOLUMES 2001 - 2007

Exhibits 3 and 4 depict the trends of basic volume for the regions in the same time frame year to year and in aggregate. Japan's basic volume again ranks the highest overall but is slowly declining. Parallel to the trend by total volume, the U.S. once again is steadily narrowing Japan's lead. Volumes of basic patents for Korea are higher than for Europe. Once again, we see China exhibits strong growth moving from last position in this group to third over the period, exceeding both Europe and Korea in 2007.

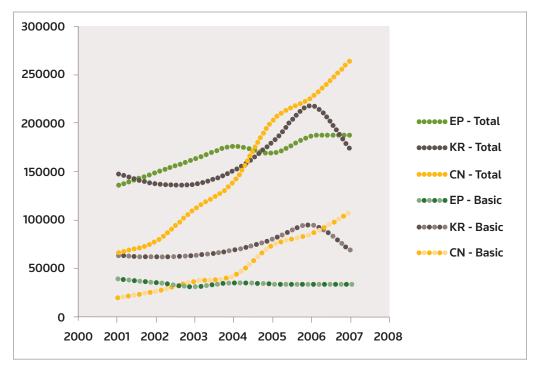


The two-year gap in China's lead over Europe and Korea between the total patent volume and the basic patent volume is worth noting (Exhibit 5). The China basic patent volume didn't exceed Europe and Korea until after 2006 while the China total volume overtook Korea in 2004. Obviously, China's growth rate relative to Europe and Korea has been more rapid in total volume than that in basic patent volume. There are two implications. First, China has been a hotbed for patent applications originated elsewhere, which pushes up the total volume. Second, China has ramped up domestic inventions, which boost the basic patent volume.

The shares of Europe and China in aggregated total volumes (both at 12%) are noticeably greater than that in aggregated basic volumes (9% and 6%). This reflects a high level of manufacturing and/or marketing interests in the regions by external entities, which enlarge the regions' share in the aggregated total volumes.

THE TWO-YEAR GAP IN CHINA'S LEAD OVER EUROPE AND KOREA BETWEEN THE TOTAL PATENT VOLUME AND THE BASIC PATENT VOLUME IS WORTH NOTING

The China basic patent volume didn't exceed Europe and Korea until after 2006 while the China total volume overtook Korea in 2004. Obviously, China's growth rate relative to Europe and Korea has been more rapid in total volume than that in basic patent volume.



BASIC VS. TOTAL PATENT VOLUME

The ratio of basic patent volume to total patent volume generally reflects patenting entities within the region, so the higher the ratio, the more filings by domestic concerns compared to external interests. As shown in Exhibit 6, the basic to total ratio ranges from the lowest of 18.1% in Europe in 2007 to the highest of 65.5% in Japan in 2001.

Japan shows a high proportion of basic to total patents indicating a predominance of filings by domestic concerns; however there is a steady downward shift each year. Japan's basic patent volume tumbles from around 66% in 2001 to just below 50% in 2007.

The U.S. is relatively stable in the ratio of basic to total patent volume, indicating that the upward trend is evenly fueled by both domestic and foreign concerns. Europe and Korea both display a varying degree of declining percentage of basic to total patent volume. By contrast, China is the only region in the group where the proportion of basics is growing steadily, from less than 30% in 2001 to more than 40% in 2007. Clearly, the domestic concerns are growing at a more rapid pace than foreign entities behind the Chinese patent boom.

Ratio of Basic Total	2001	2002	2003	2004	2005	2006	2007	Average
JP	65.5%	60.9%	59.4%	58.2%	55.9%	54.2%	49.5%	57.5%
US	49.8%	46.6%	47.8%	43.0%	48.6%	46.2%	47.0%	46.8%
EP	29.4%	24.0%	19.2%	20.3%	20.2%	18.1%	18.1%	20.9%
KR	43.2%	45.3%	46.5%	45.6%	44.1%	43.4%	40.0%	43.8%
CN	29.7%	33.6%	32.8%	30.2%	36.4%	37.8%	40.7%	36.0%

LOOKING FORWARD

Given the trends observed here, it is difficult to resist a bit of crystal-ball gazing and to speculate about the patent landscape in the not-too-distant future. Although strictly a mathematical exercise, it is interesting to observe the predictions on this basis.

Using the average annual growth rate from 2002 to 2007 (Exhibit 7) and a straight-line projection approach, we can see that the U.S. is set to surpass Japan in 2009 (Exhibit 8). China is set to surpass Japan in 2011, and then the U.S. in 2012.

The predictions from looking at volumes of basic patents projected into the future are broadly similar although the timescale is somewhat shorter (Exhibit 9). Again, the U.S. is set to overtake Japan in 2009, but here China overtakes first Japan a year earlier in 2010, and then the U.S. one year earlier in 2011.

Region	Average Total Volume Annual Growth Rate	Average Basic Volume Annual Growth Rate
JP	2.0%	-2.7%
US	14.4%	13.0%
EP	5.6%	-2.4%
KR	3.8%	2.6%
CN	26.8%	34.3%

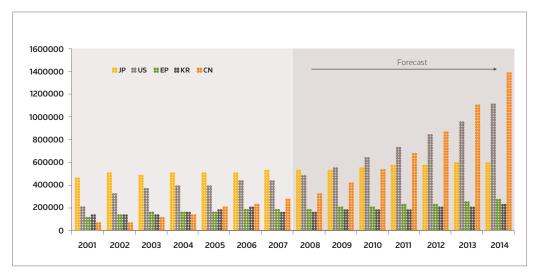


Exhibit 8

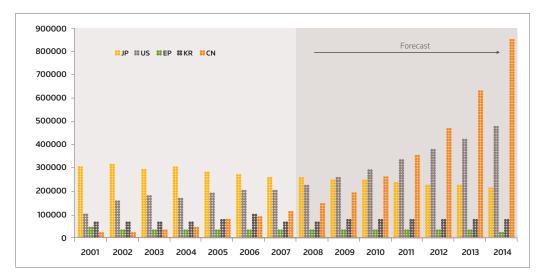


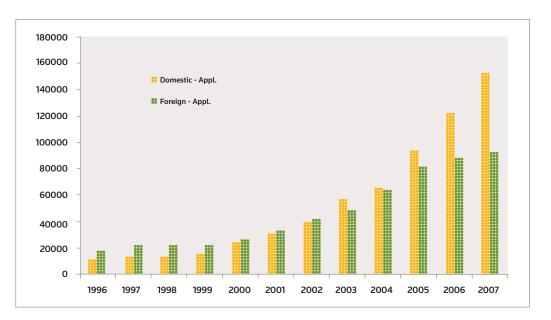
Exhibit 9

THE DRIVING FORCES BEHIND CHINA'S PATENT BOOM

DOMESTIC VS. FOREIGN PATENT APPLICATIONS

Exhibit 10 depicts the number of annual Chinese patent applications by domestic and foreign applicants, according to State Intellectual Property Office (SIPO) statistics.⁴ Both groups have trended upward. However, domestic applications grew at a more rapid pace and outnumbered foreign applications in 2003. Furthermore, margins between domestic and foreign applications have gotten wider over the last three years.

There are three phases between foreign and domestic applications: foreign outnumbered domestic from 1996 to 1999; foreign and domestic nearly reached a tie from 2000 to 2002; and foreign trailed domestic from 2003 onward. In 2006 and 2007, domestic applications exceeded foreign ones by as much as 28% and 40%. Such differences are especially impressive because they were accomplished on a base of approximately four times that when the foreign applications were greater in number. Innovations by domestic entities unquestionably have become a mainstream driving force and will continue to shape China's patent landscape.



4 Data compiled from statistics released by SIPO, http://www.sipo.gov.cn/sipo_English/statistics/index.htm.

CHINA'S INVENTION PATENT APPLICATIONS OVERSEAS

In the 2006 Chinese 11th Five Year Plan for national economic and social development, the Chinese government highlighted innovation as a focus along with social harmony, environment, macro-economic balance, and governing the market.⁵ The country's science and technology plan articulates the ambitious goal of China becoming an "innovation-oriented" society by the year 2020.⁶ Since then, China has considerably expanded its overseas invention patent applications. Exhibit 11 demonstrates that from 2006 to 2007 the growth rates of China's overseas filings in the U.S., Europe and Japan patent offices were up by 9.9%, 58% and 29.9%, respectively. This outpaced the growth rates of 6%, 3.7%, and 3% by all applicants in these offices.⁷ Given the amazing track record in the home office, China likely will sustain its overseas patenting activities to augment the country's ability to compete in global markets, despite that its overseas filings overall have been on a smaller scale.

On the other hand, China is tightening requirements for multinational companies conducting R&D in China. A new amendment will require foreign companies making discoveries in China to file for patents first in China, or risk losing legal protection for their intellectual property there.⁸ If international companies fail to file patent applications in China first for discoveries made from their local research centers, they may not be able to substantiate any subsequent patents in China and protect sales in the local market from competitors. The proposed amendments could become law in the not too distant future, which would further boost invention registrations in China.

- 5 "Abstract of the Eleventh Five-Year Plan outline," People's Daily Online, March 8, 2006.
- 6 "Innovation Tops Hu Jintao's Economic Agenda," Xinhua News, October 15, 2007.

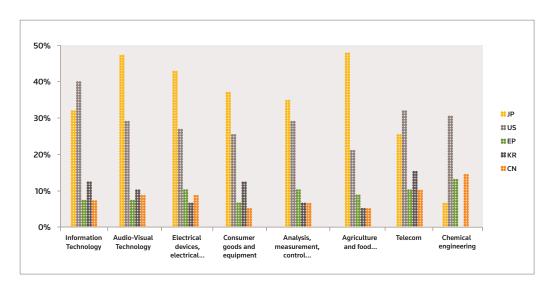
7 "Dramatic Increase of Overseas Invention Patent Applications in China in 2007," SIPO press release, March 11, 2008, http://www.sipo.gov.cn/sipo_English/news.

8 "China proposes changes to foreign company patent rules – report," Thomson Financial News, July 3, 2008.

Patent Office	Oversea Invention Applications by China in 2007	Increase from 2006 by China	Increase from 2006 by all Applications
US	4140	9.9%	6.0%
EP	1136	58.0%	3.7%
JP	656	29.9%	3.0%

SHIFT OF TECHNOLOGY FOCUS

On a worldwide scale, China's patent portfolio seems to parallel the other major patent countries/regions by technology profile. Using statistics on worldwide patent activities released by the World Intellectual Patent Office (WIPO) in 2007,⁹ we compare China with the remaining four major patent offices in selected technologies (Exhibit 12) and illustrate China's contribution in the worldwide environment (Exhibit 13).



Field	Worldwide Patent Applications 2000-2004	Worldwide Growth Relative to 2000	China Records 2000-2004	China's Worldwide Share	China's Worldwide Ranking
Information Technology	1,610,938	28%	112,766	7%	5th
Electrical Devices, Electrical	585,230	13%	38,258	8%	4th
Analysis, Measurement, Control	556,655	20%	46,818	6%	5th
Telecommunications	541,788	12%	22,055	9%	5th
Audio-Visual Technology	478,231	28%	33,399	8%	4th
Consumer Goods and Equipment	441,094	12%	5,259	5%	6th
Chemical Engineering	245,589	-7%	48,761	13%	2nd
Agriculture and Food	105,186	5%	31,927	5%	7th

Exhibit 13

The general trends are: Japan and the U.S. compete for the top two spots except in chemical engineering where Japan is behind China and Europe. China ranks in the fourth or fifth position and is within close range of Europe or Korea in technologies, except for chemical engineering which is the largest segment in China's patent portfolio. In chemical engineering, China is in second place behind the U.S.

From a historical perspective, big technological changes took place in China's patent portfolio. Exhibit 14 compares the top five largest technologies (as defined by Derwent class) in Chinese invention patent applications between 1995 and 2005. In the span of eleven years, Digital Computers shifted from fourth to first with a growth rate of 3093%. Telephone and Data Transmission Systems and Computer Peripheral Equipment applications entered the top five in 2005 vs. being less significant in 1995. The top three technologies in 1995, Natural Products and Polymers, Foods and Food Treatment, and Fermentation Industry, were heavily oriented in food production, reflecting the economy at the time when feeding millions of people was the top priority, and foreign investment and the introduction of high technology were in their infancy.

Year	Top Five Fields	Patent Applications
	Natural products and polymers	1,854
	Other foods, food treatments including additives	1,209
1995	Fermentation industry	625
	Digital computers	584
	Refractories, ceramics, cement incl. mfg.	520
	Digital computers	18,649
	Telephone and data transmission systems	12,997
2005	Natural products and polymers	9,146
	Fermentation industry	5,334
	Computer peripheral equipment	4,838

Exhibit 14

As China's economy grew, its patent portfolio became more high-tech focused, resembling the developed countries' portfolios.

A closer look at the applicants reveals that there is still a considerable gap in areas of expertise between domestic and foreign entities: foreign entities lead domestic entities by a wide margin in high technology segments while domestic applicants still dominate food-oriented categories. For instance, foreign applications in digital computers grew at about twice the pace of that of domestic, resulting in 67% of the total in 2005 compared to 54% in 1995, even though tremendous growth was seen by the domestic group (Exhibit 15).

On the other hand, the shares between domestic and foreign applications remained largely unchanged for natural products and polymers in the same period in which domestic applications account for 90% to 91% of the total while both domestic and foreign applications expand by several folds.

Digital computers	1995	2005	Growth Rate
Total	584	19,340	3212%
Domestic Applications	269	6,355	2262%
Foreign Applications	315	12,985	4022%
Domestic Applications %	46%	33%	
Foreign Applications %	54%	67%	
Natural products and polymers	1995	2005	Growth Rate
Total	1,854	9,146	393%
Total Domestic Applications	1,854 1,700	9,146 8,195	393% 382%
Domestic Applications	1,700	8,195	382%

GOVERNMENTAL POLICIES AND GOVERNMENT'S ROLE IN INNOVATION

R&D BUDGET

The Chinese government plans to dramatically increase R&D expenditure to reach the goal of 2.5 percent of GDP by 2020, compared to 0.6% in 1996 and 1.4% in 2006. In the same time, the government's economic plan targets a GDP growth rate exceeding 7.5 percent annually until 2010 and then 7 percent until 2020, yielding a huge increase of available R&D expenditure in coming years.¹⁰ A positive correlation exists between the number of patent applications and R&D expenditure by industry ¹¹ and by country/ region.¹² China's economic growth and liberal boost in R&D expenditure will continue to fuel its innovations.

TAX AND FINANCING

The Chinese government is allowing greater and easier tax deductions for R&D expenses, increased government-backed lending, and discounted interest rates to R&D investment.¹³ It seems inevitable that these vehicles will further push China's already stunning patent statistics to new heights in the coming years.

INDIGENOUS INNOVATION AND TECHNOLOGY STANDARD

Chinese premier Wen Jiabao stated that "Core technology cannot be bought. Only by strong capacity of science and technological innovation, and by obtaining our own IP rights, can we promote [China's] competitiveness and ... win respect in the international society." ¹⁴ China's science and technology policy encourages "indigenous innovation" to improve homegrown creativities and to substantially reduce reliance on foreign technologies that largely dominate the high-tech and core technological fields today. Creating technology/product standards built on homegrown patents ensures royalty payments go to local inventors. This approach is particularly prevalent in telecommunications and electronics industries, impacting a range of products including cellular telephones, digital televisions, computer chips, video discs, digital cameras and next generation networks. ¹⁵

- 10 "Technology Upgrading and China's Growth Strategy to 2020," Whalley and Zhou, 2007, 8–9.
- 11 "Study on the Trend of Research and Development from Patent Application," NISTEP, Report No. 9.
- 12 "Patents and R&D expenditure", Bernard FÉLIX, Statistics in focus Science and technology, 16/2006.
- 13 "China's R&D Policy for the 21st Century: Government Direction of Innovation", Katherine Linton, http://ssrn.com/abstract=1126651, February, 2008.
- 14 "National Strategies and Policies for Innovation: A view from China and India", WPO Magazine, July 2007.
- 15 "China Standard Time," Greg Linden, Business and Politics, Vol. 6, Issue 3, 2004.

GOVERNMENT'S ROLE IN ACADEMIA AND ENTERPRISE

In China, almost all of the major academies, including universities, colleges and scientific research institutions, are owned by the government. A Thomson Reuters study found that the Chinese academic sector contributes a significantly higher proportion of patent applications to the national total compared to many other countries: 16% compared to 1% in Japan, 4% in the U.S., and 2% in Korea, respectively. ¹⁶ The same study found that the only other country that has a high academic contribution similar to China is Russia. Both China and Russia are ruled by centralized governments where R&D project selection and funding are predominantly determined and controlled by the government.

Furthermore, the government also plays a significant and direct role in Chinese enterprises, even though this is a factor hidden from most statistics in China. In 2007 the governmental investment in about 150 of China's centrally administered state-owned enterprises (SOEs) reached 100 billion Yuan (14.27 billion USD) – 27% of national R&D total. ¹⁷

MONETARY INCENTIVE

Providing government subsidies to domestic inventors and entities is a part of the policies administered by The Chinese Ministry of Science and Technology. ¹⁸ Provincial and city governments who are eager to meet the central government's targets often allocate additional subsidies and reimbursements of fees to stimulate patent applications. In 2003, the Intellectual Property Office of one Chinese city specified grants of 10,000 Yuan to the owner of an invention patent that had been successfully registered in foreign countries or a maximum of 5,000 Yuan for a patent registered in China. In addition, the city government would fully reimburse the application and evaluation fees paid by the applicant, while the provincial government would grant another 50% subsidy based on the amount. ¹⁹ Such incentives are substantial considering that the national average annual wage in China was 14,040 Yuan (2,003 USD) at the time. ²⁰

^{16 &}quot;Analyzing Global Patenting Activity Using Strategic Intelligence and Competitive Analysis Information from Thomson Innovation, the New Standard in IP Research and Analysis," World IP Today, Thomson Reuters.

^{17 &}quot;China's central SOEs invest almost 100 bln yuan in R&D in 2007," Xinhua News Agency, July 8, 2008.

^{18 &}quot;Chinese Research Institutes Urged to Be More Patent-aware," Xinhua News Agency, May 13, 2003.

^{19 &}quot;Foreign Investors in Foshan Entitled to Patent Application Subsidies," Business Alert – China, February 3, 2003.

^{20 &}quot;High TAR wages benefit the privileged," http://www.phayul.com/news, February 11, 2005.

PATENT QUANTITY VS. QUALITY

While Chinese patent statistics continue to make headlines, both government insiders and legal experts express concerns about patent quality. A recent article in the *Financial Times* indicates that the patent figures reflect a concerted government campaign to persuade Chinese companies to protect their intellectual property by law, and that government subsidies to cover patent application costs is a factor that artificially inflates the number of filings.²¹ Chen Naiwei, director of the Intellectual Property Research Centre at Shanghai Jiaotong University, echoed the view that many local governments have provided patent fees to enterprises and science institutes, resulting in the rapid growth in applications. Most patents filed in China are for a new design appearance or new models, which do not require great technical innovation, he adds.²²

The Chinese patent office permits three types of patents: invention patents that are similar to U.S. utility patents having 20 years of protection, utility model patents that have 10 years of protection, and design patents. The utility model patents are particularly popular with domestic applicants because they are easier and faster to prepare, do not undergo substantive examinations before being granted, and cost less. ²³ For these reasons, utility model patents may be of substandard quality intrinsically.

For invention patents that undergo SIPO's examinations, there are a number of efforts and developments in place to manage quality. The majority of SIPO's more than 2,000 patent examiners have been trained by the EPO, with an additional 60 examiners per year undergoing training in various EPO centers. In the mid-1990s, SIPO adopted the EPOQUE system, an international search database for patents to facilitate shared standards of automated patent filing. In June 2007, SIPO and EPO entered a strategic partnership in which EPO will work closely with SIPO to secure Intellectual Property Rights in China and to further align the Chinese patenting system with international patenting practice.²⁴

Invention patents can be evaluated, at least in part, based on the success rate of granting from Chinese overseas applications. The results are yet to be determined and must be evaluated in the coming years.

^{21 &}quot;The value of branding becomes patent," Financial Times, July 2, 2008.

^{22 &}quot;China hits top three in patent applications," SciDev Net (http://www.scidev.net/en/news), August 15, 2007.

^{23 &}quot;Patenting Landscape in China," Evalueserve, May 2008.

^{24 &}quot;Background: EPO and SIPO move ahead to secure IPR," EPO new release, June 8, 2008.

CONCLUSION

Although the predictions of future patent application volume by the five major patent offices are purely mathematical exercises, the inescapable fact is that Chinese patents are here to stay and will continue to evolve into prominence. So what does this mean for those involved in the Chinese patent system?

For foreign companies doing business in China, the proposed amendments in patent law, which require local discoveries to be registered in China first, could have a major effect on their IP strategies. In addition, the flood of domestic inventions and the difficulties in discerning quantity from quality heighten the necessity of intelligence in analyzing and understanding what is really innovative.

For Chinese companies and institutions, being aware of prior art from developed countries to create new IP rights, especially in high-tech and core technologies, is essential.

For Chinese government agencies and quasi-governmental organizations at various central, provincial and local levels, identifying technology gaps and partners that can help to fill them is key to getting China's innovation engine on the right track.

For the information industry, both from the points of view of information providers and patent information professionals, the huge and rapidly growing volumes of non-Roman character patent information being published today, and in the future, pose one of the key challenges to be addressed.

PATENTS

Enforcing pharmaceutical and biotech patent rights in China

Y Philip Zhang and Michelle M Deng

Companies with a significant intellectual property stake in China should put in place an effective protection and enforcement strategy against local and overseas competitors.

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With a population of 1.3 billion and a rapidly expanding economy, China has become a manufacturing powerhouse and one of the largest consumer product markets in the world. Its current drug market of \$15 billion is estimated to grow by eightfold between now and 2020 and is poised to become the world's largest pharmaceutical market by 2050 (refs. 1,2), drawing enormous attention from foreign drug companies interested in selling their products in China. Many Western manufacturers are also increasingly looking to China for a place to conduct drug discovery research, clinical trials and drug production. Thus, the notion of China as "factory to the world" has come to mean a lot more than just making toys, clothing and consumer electronics. For example, China already is the largest supplier of bulk drug materials in the world³. About three-quarters of the pharmaceutical ingredients consumed in the United States are made in China⁴.

Over the past two decades, China has established a patent protection system largely resembling those found in more industrialized nations, particularly Europe. Today, China is a member of all major international conventions and agreements for the protection of intellectual property (IP) rights⁵. The current Chinese patent law provides protection for

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e-mail: pzhang@cooley.com or michelle.deng@genzyme.com compositions-of-matter, including chemicals, biologics and microorganisms, such as viruses and bacteria, as well as medical devices. Swisstype claims can be used to obtain indirect medical use coverage for these compositions. Disease diagnosis or treatment methods, and animal and plant varieties, however, are not patentable in China⁶.

IP enforcement, a major concern for innovative pharmaceutical and biotech businesses, has improved profoundly thanks in large part to the continued effort of China's central government to comply with its obligations as a member of the World Trade Organization (WTO). In addition, as Chinese pharmaceutical and biotech industries move up the value chain and begin to target higher-end drug products as well as more sophisticated and complex pharma and biotech contract research services, more effective IP protection and enforcement increase the competitiveness of these domestic industries.

Many Chinese firms have recognized the importance of innovation in the marketplace and are making strides to become innovators themselves. Interestingly, China boasts the world's first approved gene therapy product⁷. The Chinese Food and Drug Administration (SFDA) approved Shanghai Sunway's adenovirus p53 gene therapy product Oncorine for head and neck cancer treatment on April 21, 2006. A sense of urgency has gradually taken shape, which has helped China to build broader consensus among industries and governments at both central and local levels on more effective protection and enforcement of IP rights. Improvements on enforcement are especially profound in the industrialized coastal metropolitan areas.

Chinese firms now frequently file defensive and offensive patents and have begun to adopt more sophisticated IP and business strategies, including advanced technical design-around and legal challenges to third-party patents. Grant of Chinese patents increased by 30% in the first half of 2008 compared to the first half of 2007, whereas the volume of patent applications went up by 26% in the same period (Box 1). Chinese courts have also seen a steady increase of patent litigation over the years. From 2004 to 2007, the number of patent cases filed increased from 2,387 to 3,847, with an increasing annual rate of about 15% to about 20% (ref. 8). Therefore, it is important for overseas biotech and pharma industries to appreciate the current environment and future trend in IP protection and enforcement in China. For companies with a significant IP stake in China, it is advisable to put in place an effective IP protection and enforcement strategy and to understand what it would entail to successfully enforce one's IP rights in China, be it against local or overseas competitors.

Patent rights and infringement in China

The general scope of patent protection offered under Chinese patent law is similar to what is typically provided under United States or European patent law. Article 11 of the Chinese Patent Law prohibits unauthorized making, use, offer for sale, sale or import of a patented product. The provision also prohibits the unauthorized use of the patented process (and use, offer for sale, sale or import of products directly obtained by the patented process) for production or business purposes⁹.

There are, however, exemptions to the patent rights, some of which are more pertinent to biotech and drug patents¹⁰. First, the Chinese patent law provides prior use rights. If one has already made an identical product, used an identical process or made necessary preparations for its making or using before the filing date of a patent, the person having such

Box 1 A future IP powerhouse?

In 2007, China became the third largest patent-filing country in the world behind only the United States and Japan in terms of number of annual patent filings. If China maintains its current growth rate of new patent filings, it would overtake the United States and become the world's leading patent-filing nation by 2012. China has maintained a stunning 20% average annual growth rate in new patent filings over the last 15 years. For the first half of 2008, invention patent filings (that is, excluding utility model patents) have reached 132,088, representing a 26.6% increase over the same period in 2007. Patent grants are also increasing at a fast pace. The grant of new patents by the SIPO reached 41,752 in the first half of 2008, a 30.3% increase over the same period last year. A large portion of the increase was due to patent filings by Chinese entities. The dramatic increase in invention patent filings in 2007 over 2006 were mostly due to increased filing activities by domestic entities (25.1%) rather than by foreign entities (4.5%). Chinese domestic share of the total patent filings has continued to increase over the years, representing 62% of all Chinese invention patent filings in 2007.

In the technical areas of biotech and pharmaceuticals (including cosmetics according to International Patent Classification), Chinese entities take up 79% and 64.5% of filings at SIPO in the respective technical areas, indicating strong domestic interest in biotech and rapid growth in R&D output.

Chinese entities are also increasingly filing patents in foreign countries. The last wholeyear statistics show that China's Patent Cooperation Treaty (PCT) filings (a principal route for foreign filing) increased by 38.5% in 2007, whereas in the same period the US and Japan's PCT filings grew at 3.7% and 2.6%, respectively.

Noticeably, however, China still has a long way to go to catch the United States in foreign filings, which generally represent technologies having significant commercial value. In 2007, US PCT filings represented 33.6% of all PCT filings (albeit down from 40.8% in 2000) whereas China's PCT filings account for only 3.5% of the total (up from 0.8% in 2000). For the first quarter of 2008, China accounts for only 1.7% of all PCT filings worldwide in the pharmaceuticals field (including cosmetics) while the United States takes a dominant 39% share and Japan, 11.2%. In the areas of biotech and pharmaceuticals, the United States, Japan and several European countries continue to dominate, although China and the Republic of Korea are catching up at a fast pace.

As an International Search Authority, the SIPO also lags far behind the European Patent Office (EPO) and the US Patent and Trademark Office (USPTO). The EPO is selected by 47.1% of PCT applicants as their preferred search authority, whereas the USPTO takes up 18.7% of the share. SIPO's share in 2007 was only 3.5%, which, however, represents a 70% growth over 2006.

Source: All data extracted from WIPO Statistics Database.

prior use may continue to make or use the patented invention, albeit such future use must be restricted to the scope of the prior use.

Second, any person may use a patented invention solely for the purposes of scientific research and experimentation. It is not entirely clear, however, what would constitute pure scientific research and experimentation under the Chinese patent law. The Supreme People's Court has interpreted Article 63(4) as providing exemption to research and experiments where the patented product or process is used for the purposes of investigating, validating or improving the patent itself¹¹. This exemption also applies to situations where one makes or uses the patented product or process in clinical trials during drug regulatory approval. It is likely that the Chinese courts will take into consideration these proposed interpretations to allow some level of exemption for clinical trial activities in connection with regulatory approval of pharmaceutical products. Because the above interpretations have not been formally approved, however, it remains to be seen whether a protection comparable in scope to those offered by the United States and Europe will be provided. In the United States, an activity is exempt from infringement if it is reasonably related to the development and submission of information under a federal law regulating drugs or biological products¹². In Europe, a similar safe harbor is provided for activities such as clinical trials and other necessary studies, although the scope is less well defined¹³.

Significantly, the lack of knowledge of patent infringement may also be an effective defense to infringement in China. This exemption clearly affects a drug patent owners' ability to enforce patents against pharmacies and distributors, for example. Under the Chinese law, one is not liable for the damage to the patentee if one obtained the infringing product from a legitimate source without knowing that the product had been made and sold without the authorization of the patentee¹⁴. The law also expressly provides for patent exhaustion after the first sale of an authorized product¹⁵.

Patent enforcement in China

Generally speaking, when a patentee considers enforcing his patent rights in China, there are two avenues. Under the Chinese law, he may seek judicial enforcement by filing a complaint in a People's Court having jurisdiction over the alleged infringer or the infringing activity. Alternatively, the patentee may seek administrative enforcement by filing a request with a local Administrative Authority for Patent Affairs, sometimes called Intellectual Property Bureau (IPB), that has jurisdiction over the alleged infringement act¹⁶. Depending on the objective of the patentee, either or both of these mechanisms could be used, separately or in combination.

Administrative enforcement. IPBs are set up by local governments, such as provinces, autonomous regions and major municipalities under direct administrative control of the central government, or at a lower level of government that has the need to set up a special office to handle patent matters, typically large or midsized cities or large counties¹⁷. A patentee may seek administrative relief at a local IPB having proper jurisdiction, which typically means the IPB office where the infringer resides or where the infringement took, or is taking, place. Sometimes, more than one IPB could have jurisdiction over a matter, in which case one can file in either IPB¹⁸.

Once patent infringement is established, the IPB may issue an administrative order requesting the infringer to immediately stop the infringing act. The infringer may appeal to an appropriate People's Court to seek the overturn or modification of the administrative order. If, within the allowed time limitation, no appeal has been filed and the administrative order is not complied with, the IPB may approach the People's Court for a compulsory execution of the administrative order.

Although an IPB is authorized to decide on IP infringement, remedies available from an IPB are limited by Western standards. For instance, it does not have authority beyond issuing injunctive orders and fines of up to three times the illegal income or RMB 50,000 Yuan (about \$7,300) if no illegal income could be ascertained¹⁹. The IPB may, upon the request of the parties, mediate the amount of compensation for the damage caused by the patent infringement. If such mediation fails, 02 © 2008 Nature Publishing Group http://www.nature.com/naturebiotechnology

the parties may initiate legal proceedings in the People's Court having proper jurisdiction, and the court will determine the amount of damages and other relief.

Administrative enforcement is relatively fast, cost efficient and mostly ex parte. A patentee seeking administrative enforcement, however, should recognize the possibility that the administrative enforcement process could be (and often is) influenced or compromised by local politics or corruption. Also, there is no formal discovery procedure available to the patentee who may be completely dependent on the authority in evidence collection when evidence is not attainable through public channels. Additionally, if the administrative panel that is put together to decide the complaint lacks proper legal or technical experience and expertise, it could certainly affect or delay the outcome, especially in complex pharma or biotech patent cases.

Administrative enforcement may involve law enforcement, such as on-site inspections or even police raids of an alleged infringer's business in an effort to seize or preserve evidence of infringement. Local authorities may be under pressure to protect local businesses. A well-built network of guanxi (that is, personal, financial or political connections that allow one to gain advantages over those who do not possess such relationships) could protect the alleged infringer and make it difficult to obtain and enforce an injunction. In addition, when the other side is well connected in local politics, it may be advisable for the patentee to forego the limited amount of fines and seek a settlement that better achieves its strategic goal.

For pharmaceutical or biological products that are protected by composition-of-matter patents, such as compound, formulation or device claims, administrative enforcement should be considered before instituting judicial enforcement, as evidence collection and determination of infringement is relatively straightforward. In enforcing a methodof-manufacture patent for a pharmaceutical or biological product not protected by a composition-of-matter patent, it could be difficult to ascertain the exact method by which an alleged infringer has made or is making his product. For instance, he could have parallel processes in-house and display only the legitimate process to the authority during an inspection. Also, technical issues could impede the process as some biological and chemical patents are complex and the claim scope is not readily defined. The IPB may opt to request the parties to participate in mediation and encourage settlement between the parties rather than issuing an injunctive order.

During an administrative process, the alleged infringer could petition the Patent Reexamination Board (PRB) to invalidate the asserted patent. He may request the IPB to suspend (that is, stay) the administrative proceedings pending resolution of the invalidation proceedings before the PRB. The IPB is required to consider the request for stay but is not obligated to grant stay as of right²⁰. Thus, it is possible for the administrative proceeding to result in a finding of infringement followed by a patent invalidity finding by the PRB.

Judicial enforcement. China's judicial system is comprised of four tiers of courts, together known as People's Courts. At the lowest tier are the Basic (or Primary) People's Courts that mostly serve as the trial courts for the majority of civil disputes and criminal prosecutions. Each administrative county or district is likely to have one or more Basic People's Courts. At the next level are the Intermediate

Administrative enforcement may involve law enforcement, such as on-site inspections or even police raids of an alleged infringer's business in an effort to seize or preserve evidence of infringement.

People's Courts, which exist only in large cities or provincial capitals and mostly hear appeals from the trial courts. The Intermediate People's Courts also serve as courts of the first instance for certain specialized matters. At the next level are the High People's Courts. Each province, autonomous region and city under direct administration of the central government (that is, the cities of Beijing, Shanghai, Tianjin and Chongqing) has one High People's Court, which is the highest court within the respective province, region or city. At the top of the court system is the Supreme People's Court, the court of last instance. Within the Supreme People's Court, there are specialized IP chambers that handle IP-related matters.

For patent infringement matters, a select few courts—usually Intermediate People's Courts—are designated as the trial courts. In general, jurisdiction of a court is based on the domicile of the defendant or the location of the alleged infringing activity. As a result, a patent infringement action sometimes may be filed in more than one court.

As administrative or judicial enforcement of patents often trigger invalidation proceedings at the PRB, judicial review of the PRB's decision is critical in the fight over validity of a patent. The Chinese Patent Law allows the parties to appeal the decisions of the Sino-Intellectual Property Office (SIPO), such as invalidation actions by the PRB, to the Beijing No. 1 Intermediate People's Court. Further and last-instance appeals may be taken to the Beijing High People's Court. Appeals may also be taken to the IP Chambers of the Supreme People's Court on matters related to injunctions and damages.

Legal proceedings concerning patent infringement must be filed within two years of the date on which the patentee or an interested party obtained or should have obtained knowledge of the infringing activities²¹. In the case of a published patent application that later issues, the time limitation for filing legal proceedings concerning patent infringement is two years from the date on which the patentee obtains or should have obtained knowledge of the exploitation of his invention by another person. However, where the patentee has already obtained or should have obtained knowledge before the date of the grant of the patent right, the prescription is counted from the date of the grant.

The burden of proof of patent infringement typically resides with the plaintiff patentee or interest holder. The patentee must collect and submit evidence of infringement and the amount of damages contributable to the infringing act.

There are exceptions, however, on the burden of proof in cases where the asserted patent concerns a method or a process of manufacture of a new product. In such a situation, the defendant denying infringement is required to present evidence of noninfringement²². Therefore, one important early determination in litigation involving manufacturing method claims is to determine whether the relevant product is a new product under the patent law.

Many products Western biotech and pharma companies market in China are innovative products that often fall under the new product category. A new product is defined as one that had not appeared on the Chinese domestic market before the application of the patent at issue. The new product, when compared with similar products on the market before the application of the patent, has to be clearly different in its composition, structure, quality, feature or function²³.

Although the burden of proof can be shifted to the alleged infringer, it is only allowed after the patent holder proves that the product made according to the patent is a new product; and the product obtained by the accused infringer is the same as that produced according to the patented method²⁴. A court takes account of trade secret considerations when requiring the alleged infringer to prove that its manufacturing method differs from the patented process for the new product. The burden of proof is of a limited scope necessary to prove such difference, but not the entire manufacturing process or all methods used²⁵. As long as the alleged infringer can prove that one technical characteristic of its product manufacturing process is not the same or equivalent to the corresponding step required by the claimed method, no patent infringement can be established.

In China, there is no formal discovery mechanism for evidence collection as it is available in the United States. Interrogatories, depositions and document production that are routinely available to the parties in a patent litigation in a US district court are not available to the litigants under the Chinese judicial system. Courts, however, may impose orders (for example, pre-trial injunctions) to a party to cease infringing activities and orders for evidence collection, submission and preservation. Although the effectiveness of such orders is questionable, for example, where physical control of the activity or evidence of infringement is difficult or impossible, such orders do provide some access to evidence of infringement or the infringing products.

Judicial enforcement provides the patentee the potential for preliminary injunctions, permanent injunctions and monetary damages. The patentee or interest holder may, before any legal proceedings are instituted, request a court to order the suspension of relevant activities and the preservation of property and evidence. To obtain such an order, one must show evidence to prove that another person is infringing or will soon infringe one's patent right and that, if such infringing act is not checked or prevented from occurring in time, it is likely to cause irreparable harm to the patent holder. The standard for preliminary injunctions is centered on existing or imminent infringement (that is, likelihood of success on the merit of infringement and the existing or immediacy of infringing activity) and irreparable harm²⁶. Permanent injunctions are available upon a finding of infringement by the court.

The amount of monetary compensation is assessed on the basis of the losses suffered by the patentee or the profits the infringer has earned through the infringement. Where it is difficult to determine the losses that the patentee has suffered or the profits that the infringer has earned, the compensation amount may be assessed by reference to the appropriate multiple of the amount of the exploitation fee (that is, license fees and royalties) of that patent under a contractual license²⁷. The statutory damage, imposed when the above methods cannot be applied, is RMB 500,000 yuan (or about \$73,000)²⁸.

Unfair competition is an additional cause of action that often accompanies the allegation of patent infringement. Information and materials the alleged infringer uses in promoting its product may be evidence for proving unfair competition. In *Jiangsu Hengrui Medicine Co. Ltd. v. Aventis Pharma (the High People's Court in Shanghai, 2007)*, the court found that Hengrui did not infringe Aventis' patents. Hengrui, however, lost on the grounds of unfair competition for making untrue statements in advertising its cancer therapy drug. The court ordered Hengrui to publicly apologize to Aventis and pay RMB 100,000 Yuan (or about \$14,600) to Aventis.

Invalidation challenge before the PRB

As invalidity of a patent is an effective defense against a charge of infringement, an accused infringer often files an invalidity challenge

Judicial enforcement provides the patentee the potential for preliminary injunctions, permanent injunctions and monetary damages.

against the patent following an administrative or judicial enforcement action by the patentee or an interested party. Defending validity of the patent, therefore, is critical to a patent holder in a successful patent enforcement.

Procedure and venue. During the life of a patent, any party, either an entity or individual, may petition the PRB to declare the patent right invalid²⁹. At the request of a party, the PRB may decide to hold an oral hearing regarding the invalidity challenge. The PRB is required to promptly make a decision regarding the validity and notify the petitioner and the patentee of its decision. A decision declaring the patent invalid will be registered and announced by the SIPO³⁰. Either the petitioner or the patentee may seek review of the decision by an appropriate People's Court (for example, Beijing No. 1 Intermediate People's Court)³¹.

Grounds for invalidity. Basis for invalidity includes any grounds that, if properly considered, would have resulted in non-grant of the patent at issue, such as lack of novelty, lack of inventive steps, insufficiency of disclosure, etc.³².

The standard for patentability under the Chinese patent law is similar to that under US

or European laws, that is, the invention must be novel, inventive and possess practical applicability. China's patent protection is a first-to-file system. Novelty means that, before the date of filing, no identical invention or utility model has been publicly disclosed in publications or has been publicly used or made known to the public by any other means in the country, nor has any other person filed previously with the SIPO an application that described the identical invention or utility model and was published after the date of filing³³. Article 24 of the Chinese Patent Law allows a limited six-month grace period with regard to the following public disclosures: (i) where it was first exhibited at an international exhibition sponsored or recognized by the Chinese government, (ii) where it was first made public at a prescribed academic or technological meeting or (iii) where it was disclosed by any person without the consent of the applicant.

Inventiveness exists where, as compared with the technology existing before the date of filing, the invention has prominent substantive features and represents a notable progress and that the utility model has substantive features and represents progress³⁴. Practical applicability means that the invention or utility model can be made or used and can produce effective results³⁵.

Similar to the patent laws of industrialized countries, the Chinese patent law also requires sufficiency of disclosure and written description. The patent specification must set forth the invention in a manner sufficiently clear and complete so as to enable a person skilled in the relevant field of technology to carry it out³⁶. Also, as one would expect, an applicant may not amend an application beyond the scope of the original disclosure contained in the initial description and claims³⁷. Deposition of a sample may be required, similar to under patent laws of other countries, where the patent concerns a new biological material that is not available to the public and cannot be described in the application in such a manner as to enable the invention to be carried out by a person skilled in the art³⁸.

Effect of invalidity. If a patent is declared invalid, it is deemed to be nonexistent from the beginning. However, the decision declaring the patent right invalid has no retroactive effect on any judgment or ruling of patent infringement that has been pronounced and enforced by the People's Court before the invalidation. For example, a later decision for invalidity does not affect any prior decision of patent infringement that has already been complied with or compulsively executed or on any patent license or assignment that has been performed before the declaration of invalidity of the patent right39. An exception is that any damage caused to other persons in bad faith on the part of the patentee must be restituted.

Regulatory protection for pharmaceuticals

The Chinese Food and Drug Administration (SFDA) was formally established in 2003, following the model of the US Food and Drug Administration (FDA)⁴⁰. The SFDA is authorized to review and approve clinical trials, pharmaceutical and biologic products, as well as to review and issue administrative protections and quality enforcement. Besides protection for pharmaceuticals from patents, several regulatory and administrative protection mechanisms may offer additional protection.

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Administrative protection. In 1993, China adopted Regulations on Administrative Protection for Pharmaceuticals⁴¹. These regulations were put in place primarily to remedy the lack of patent protection for foreign pharmaceuticals under the then-effective patent law⁴². The administrative protection provides for exclusive right to market the drug in China. It is available, however, only to applicants from countries or regions that have bilateral treaties or agreements with China on administrative protection for pharmaceuticals43.

Administrative protection is available if the following criteria are met for a pharmaceutical: (i) it was not subject to protection by exclusive rights in accordance with the provisions of the Chinese Patent Law before January 1, 1993; (ii) it is subject to an exclusive right to prohibit others from making, using or selling it in the country to which the applicant belongs, which was granted after January 1, 1986 and before January 1, 1993; and (iii) it has not been marketed in China before the date of filing the application for administrative protection⁴⁴. Except under special circumstances, the authorities are required to complete a review of the application for such administrative protection within six months of application45.

The term of the exclusive administrative protection starts on the date when the certification of administrative protection is issued and remains in force for seven years and six months⁴⁶. The holder of an administrative protection may petition relevant government or judicial authorities to stop any entity, such as a generic firm, that is in violation of the exclusive protection47.

Administrative protection may also terminate under any of the following situations: (i) where the exclusive right of a pharmaceutical had been invalid or had lost efficacy in the country to which the applicant belongs; (ii)

where the holder of the administrative protection does not pay the required annual fee; (iii) where the holder of administrative protection abandons the protection by a written declaration; or (iv) where the holder of the administrative protection does not apply for market approval within a year from the date of the certificate of protection48.

New drug monitoring period exclusivity.

Another regulatory protection for an SFDAapproved new pharmaceutical or biological product is in the form of a monitoring-period exclusivity49. A drug product is deemed new if it has not been previously approved in China. For such a product, a monitoring period is imposed by the SFDA so that it can monitor the efficacy and adverse effect of the new drug. During the monitoring period, which ranges up to five years from the SFDA approval, the SFDA will not approve another product that is the same as the new drug unless the approved new drug

Overseas pharmaceutical and biotech firms have a lot to gain or lose from the rapid growth and modernization of China's pharmaceutical and biotech industries and markets.

is not produced within two years after the grant of the monitoring period⁵⁰. To the innovative drug companies, therefore, the three-to-fiveyear monitoring period exclusivity is available independent of patent protection.

Data exclusivity protection. Under China's Drug Administration Law, data submitted by applicants for market approval of new chemical entities are protected from use by third parties for six years from the date of approval of the new drug⁵¹. This form of protection has the effect of delaying generic competition to new chemical entities for the period of data exclusivity. In this regard, this form of protection is similar to the data exclusivity protection available in the United States under the Hatch-Waxman Act and in Europe under EU Directives 2001/83/EC (ref. 52). In the United States, data exclusivity is five years for new chemical drugs, and new legislative initiatives are pending with regard to biological drugs⁵³. In Europe, this protection period for pharmaceuticals is ten years.

After the expiration of the data protection period, a generic firm will be able to use certain data of the prior approval in its application for a generic equivalent. Similar to requirements in the United States and Europe, a generic application in China is required to declare noninfringement of valid patents of innovative drugs as of the date the generic firm seeks market approval for the follow-on version⁵⁴. Under the current provisions, follow-on biologics cannot register as generic drugs. Instead, the procedure for new drug registration must be followed⁵⁵.

Conclusions

China is undergoing rapid and major transformations in many aspects, and IP protection and enforcement is no exception⁵⁶. Overseas pharmaceutical and biotech firms have a lot to gain or lose from the rapid growth and modernization of China's pharmaceutical and biotech industries and markets. Practical and effective IP protection and enforcement strategies should be an integrated part of the overall China strategy.

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35. *Id.* 36. Art. 26, supra.

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- 39. Art. 47 of Patent Law of the People's Republic of China (2000).
- 40. The SFDA was as a restructured agency from its predecessor, China State Drug Administration, which was established in 1998 from the merger of the Ministry of Health's Department of Drug Administration with the State Pharmaceutical Administration of China.
- 41. Approved by the State Council and promulgated by the State Medicine Administration in December, 1992, and became effective as of Jan. 1, 1993.
- 42. Art. 1 of Regulations on Administrative Protection for Pharmaceuticals (1993).
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- 44. Art. 5, supra.
- 45. Art. 11, supra
- 46. Art. 13, supra
- 47. Art. 19, supra.
- 48. Art. 15, supra.
 49. Art. 66, Provisions for Drug Registration (SFDA Order

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- 50. Art. 71 and Art. 69, supra
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- 54. Art. 18 of Provisions for Drug Registration (SFDA Order No. 28, 2007).
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- 56. According to SIPO, the third major reform to China's Patent Law is expected to go into effect in early 2009. <http://www.sipo.gov.cn/sipo2008/yw/2008/200807/ t20080731_413639.html>

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Beat the first filing blues in China

More and more brand owners are discovering that someone else has managed to register their trade marks in China. **Catherine Sun** explains how they should deal with the problem

growing number of domestic trade mark owners are becoming adept at playing first-to-file games with their foreign counterparts. This trend is borne out by the statistics: over the past three years, foreign brand owners have filed more than 70,000 trade mark applications each year in China, both directly and using the Madrid Protocol. Their Chinese counterparts have filed about 600,000 applications every year, which makes foreign filing about 10% of domestic annual filing. Statistics also show that in 2005 there were 1,374 trade mark invalidation actions filed at the Trademark Review and Adjudication Board (TRAB) by domestic brand owners. However, foreign brand owners filed 895 cases at the TRAB that year, which is more than 65% of domestic cases. These numbers indicate that foreign trade mark owners face and initiate more trade mark disputes in China than their domestic counterparts proportionally. A growing number of these cases are the result of Chinese companies and individuals registering trade marks that belong to foreign businesses. This partly explains why such a high percentage of invalidation cases have been filed by foreign brand owners in China.

Unlike most common law jurisdictions, China follows a first-to-file system for trade mark registration, which means that whoever files first at the China Trade Mark Office (CTMO) gets the mark. Although the first-to-file principle is straightforward and not difficult to understand, in practice a number of foreign brand owners still fail to file at the CTMO first. However, there are a number of remedial measures available in China for foreign mark owners after someone else has filed first at the CTMO.

Who normally files a foreign mark first? In most cases, it is the foreign brand owner. But for contested cases, it is usually someone who has a certain interest in the mark, such as competitors in the same industry, former employees, consultants, agents, distributors or customers. Sometimes it is professional trade mark investors who have a number of marks available for sale. It is more difficult to deal with the former than the latter.

Is it possible to claim the mark back? The answer is yes, but at a much higher cost. To illustrate what options are available, this article uses a hypothetical scenario to illustrate issues and solutions.

Yummisty - a tasty trade mark tussle

In this scenario, a Delaware based company, CBA Corporation (CBA) has been making bread machines (a simple way to bake bread) for more than 100 years and has been using the mark Yummisty the whole time. The mark Yummisty has been registered in the US and some other countries, but not in China. Five years ago, CBA started to export the machines to the Chinese market through a Chinese distributor, Mianbao Machinery Corporation (MMC), based in Guangzhou. CBA authorized MMC to be its exclusive distributor in China under a standard distribution agreement. At the time, CBA did not want to invest a lot in China so it did not spend money in areas such as IP protection. Because it had been using Yummisty outside China for more than 100 years, CBA did not understand the need for – and urgency of – registering the mark in China.

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One-minute read

Die of the most easily avoidable, but nevertheless common, problems that brand owners face in China is finding that another party has already registered their trade marks. As China has a firstto-file system for trade marks, this can create a big problem for IP owners. Catherine Sun sets out a typical scenario involving a US bread making company whose distributor in China has already registered the English and Chinese versions of its trade mark and is copying the company's machines. Sun explains the classic mistakes the company has made and outlines the steps it needs to take to remedy the situation. These involve a series of administrative opposition, invalidation and cancellation actions, as well as going to court and ensuring that that the trade marks are recognized as well known.

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As Yummisty is such an awkward name for sales staff at MMC to spell as well as to communicate to customers in China, from day one MMC started to use the transliteration of Yummisty into Chinese. The characters used for this transliteration are 好吃极, which means very yummy tasting. During the first two years of their cooperation, CBA and MMC seemed to get along just fine. MMC was selling about 10,000 machines every year at \$1,000 for each machine. However, in year three, sales fell to 3,000. This alerted CBA, which dispatched the sales manager John Doe to visit MMC. During Doe's trip to China, he also visited some customers in Beijing, Shanghai and Guangzhou, and was shocked to see that MMC had actually been making the machine itself with

the Chinese mark 好吃极, that MMC had been selling its own (very similar) machines to CBA's customers and that the MMC machines cost only \$500. All this meant that customers had started to buy MMC's cheaper machines, which had led to the drop in sales of CBA machines in year three.

CBA's management decided to terminate the distribution relationship with MMC and issued a letter to that effect. In the letter, CBA also demanded that MMC immediately stop using CBA's trade marks Yummisty and 好吃板. Out of frustration with MMC, CBA decided to set up its own shop in China in year four. After almost a year's due diligence and preparation, CBA set up CBA WFOE (a wholly foreign-owned enterprise) in Shanghai Zhangjiang New High Technology Park.

During the registration of the WFOE, CBA was advised that it could contribute about 20% of its intellectual property as capital to reduce cash investment. At that point, CBA's global trade mark counsel Peter Careful got involved. To his surprise, both Yummisty and 好吃极 were not available for registration in China due to prior applications. Through a local agent, Careful was provided with a report that revealed that MMC filed an application for the mark 好吃极 in year one in class 7 (food machines) and class 43 (food catering services) and obtained a registration in the same year. The report also showed that MMC had filed an application for the mark Yummisty in year three in classes 7 and 43. The Yummisty mark has just been published for opposition and is due to issue in three months. The management of CBA is very concerned and wants to get both marks back at all cost. It is now seeking advice as to how it can do that.

Three key steps

Unless CBA can negotiate an assignment of the marks at issue with MMC, or abandon use of the marks in China, it will have to take multiple actions to resolve the situation.

File the trade marks in China anyway

Assuming CBA is successful in the opposition or invalidation actions against MMC discussed below, it still cannot obtain ownership of these trade marks in China. To try and ensure a complete victory, CBA needs to file several applications in China knowing that the CTMO may reject them based on the prior application or registration by MMC. These applications could include Yummisty, 好吃极 and Yummisty and 好吃被 combined. If CBA would like to come up with a different name for Yummisty, it should also file that Chinese equivalent mark. Note that MMC filed trade mark applications in both classes 7 and 43 as it also entered into the food catering business. Since CBA has never been involved in the catering industry outside or inside China, it would be difficult to win the argument that Yummisty as a service mark was well known at the time of MMC's filing.

CBA should also prepare to appeal any rejection decision of these applications with the TRAB so that the appeals could be consolidated with the opposition and invalidation actions discussed below.

Oppose, invalidate or cancel the rival registrations

An opposition may be filed within three months less one day after the date of publication. Since the Yummisty application has been published for opposition, CBA should be able to file an opposition with TRAB in time. Oppositions are most com-

It is critical to have Yummisty recognized as a well-known mark in order to win opposition and invalidation actions

> monly based on the grounds that the mark is identical with or similar to either another registered mark covering identical or similar goods, or a mark that is well known in China. Therefore, in order for CBA to win, it will have to argue the Yummisty mark was well known in China at year three when the mark was filed for registration by MMC. However, CBA can only establish well-known status in class 7 not class 43, so it may be stretching things to oppose the Yummisty mark application in class 43.

> Within five years of the registration of a mark, any party can file a petition with the TRAB to invalidate the registered mark on substantially the same grounds as for oppositions, but not where the same arguments have previously failed in an opposition for the same mark. If the petitioner is the holder of a well-known mark in China, the five-year statute of limitations can be extended if the registrant acted in bad faith when registering the well-known mark in China.

> At any time after grant, any party may file a petition with the TRAB to cancel the registered mark on the grounds that the trade mark holder violated certain trade mark regulations after registration. Such violations may include any of the following: failing to use the mark for three consecutive years; altering, or adding to, the mark; making an unrecorded assignment of the mark; and infringing on another party's copyright, design patent, well-known trade mark, or other prior rights, when the infringement has been confirmed by a final judgment. Cancellation on the grounds of non-use or improper use is not limited to the five-year statute of limitations. CTMO may also initiate a cancellation proceeding *ex officio* if it finds non-use or improper use during an administrative enforcement action.

> In the present case, since the mark 好吃极 was registered in year one, it is still within the five year period and an invalidation request can be filed. But it is hard to argue that the mark was well known at the time of filing as neither MMC nor CBA had used this mark in China at year one. CBA may argue that MMC registered this mark in bad faith, and also the mark was a translation of the well-known mark Yummisty. Arguing that MMC registered the Yummisty mark in bad faith may be easier given the fact that Yummisty is a new and unusual word, and MMC was a former distributor and applied for registration when the distributorship was terminated. Again, arguments in relation to class 43 would be difficult.

> If CTMO renders an unfavourable decision in an application, opposition, invalidation, or cancellation action, an

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appeal can be filed with the TRAB within 15 days of the initial decision. If the interested party is dissatisfied with the appeal decision, it may, within 30 days from receipt of the decision, file a lawsuit with the Beijing No 1 Intermediate People's Court.

In the present case, the CTMO and TRAB are likely to consolidate all the above appeals, opposition and invalidation actions together since they are related to the same parties.

Use the courts

CBA may consider filing civil lawsuits based on breach of contract, unfair competition or trade mark infringement. But it first needs to clean up MMC's inventory. If it fails to do this the courts may not be willing to accept the case(s), as MMC may argue it is still disposing of the inventory as a result of the previous distribution relationship. The court actions would also need to establish the well-known status of Yummisty and/or its Chinese transliteration 好吃极. CBA may also consider administrative actions based on false advertising, or a criminal action based on trade mark infringement.

The three big mistakes

CBA should have filed Yummisty and its Chinese equivalent mark before going into China

There were three reasons CBA failed to do this. First, as it had used Yummisty in the US and also registered the mark in a number of jurisdictions, CBA thought there would be no problems in China. Secondly, China was a new market and the management was reluctant to spend money on trade mark or patent filing there. Thirdly, the management did not believe that IP was enforceable in China. Of course, one possible other reason would be pure oversight and unfamiliarity with the rules.

CBA should have included a provision in the distribution agreement with MMC stipulating that all intellectual property - including the trade marks associated with the product used or intended to be used by MMC - belong to CBA, and that MMC will not register any trade marks and patents based on that licence or use them without CBA's prior written consent

The distribution agreement signed between CBA and MMC was a standard one based on CBA's US version. It did not specifically restrict the distributor from filing patents and trade marks based on the licensed products. Therefore, it would be hard for CBA to argue that MMC had breached the distribution agreement by filing both marks with the CTMO.

CBA, at the time of terminating the distribution agreement, failed to stipulate how to dispose of the inventory of Yummisty machines in MMC's possession

During year four and five (after the termination of the distribution agreement), CBA was still marketing and selling Yummisty machines and, when questioned, claimed that it was trying to dispose of the inventory. Had CBA offered to purchase the inventory back at the time of termination. CBA would have had a clear cause of action based on breach of contract which would also have helped CBA's trade mark cases by showing bad faith. If the inventory is not cleared after termination of a distribution agreement, the Chinese courts will not normally accept a case for trade mark infringement, unfair competition or breach of contract based on the continued sales of the product bearing the mark subject to the distribution agreement.

public; the period of continuous use of the mark; the period, extent and geographical scope of the continuous marketing of the mark; the previous history of protection as a well-known mark; and other factors that demonstrate the mark's well-known status.

A previous adjudication will be an important factor in the well-known mark owner's favour should future readjudication occur. Relevant supporting documents should normally cover a three-year period before the filing of the mark at issue. Therefore, in the present case, the Yummisty mark has a higher chance of being deemed to be well known in year three than its Chinese equivalent mark 好吃极 in year five.

In 2007, there were a total of 197 well-known marks recognized, of which 130 were recognized through trade mark administrative actions. 16 through trade mark oppositions and 51 through trade mark invalidation actions. Until March 25 2008, there were 228 well-known marks recognized, of which 136 were through trade mark administrative actions, 33 through trade mark oppositions and 59 through invalidation actions. Statistically speaking,

Establishing well-known status

It is critical to have Yummisty recognized as a well-known mark in order to win opposition and invalidation actions (and ultimately to get the mark registered), as well as to win any civil and criminal trade mark infringement actions.

A mark constituting a copy, imitation or translation of an unregistered well-known mark for identical or similar goods or services which is likely to cause confusion will not be granted registration or will be prohibited from being used in China. For an unregistered well-known mark in China, the owner can prevent others from registering an identical or similar mark on identical or similar products to avoid likelihood of confusion.

Under the law, a petition for the sole purpose of adjudicating well-known status is not allowed. As a prerequisite to requesting a court to adjudicate or readjudicate well-known status, there must be a pending civil or criminal trade mark action. Before requesting the State Agency for Industry and Commerce (SAIC) and CTMO to adjudicate or readjudicate well-known status, there must be a pending trade mark opposition, invalidation or cancellation action, or a pending administrative action. The adjudication is valid for three years.

The criteria specified under Article 14 of the Trademark Law of the People's Republic of China for recognizing wellknown marks are the same for both the administrative authorities and the courts: the awareness of the mark by the relevant



it seems that the chance of being adjudicated well known is higher in administrative actions than in TRAB actions.

The question of bad faith

Is it ethical and lawful to file a mark that has been used by someone else in a foreign country? The answer is not black and white and the burden of proof normally rests on the foreign brand owner to establish bad faith, which is often difficult to prove. The first-to-file system favours the first filer over the first user. There could also be an added twist in this first-to-file game, depending on whether the Chinese transliteration of the foreign mark has been registered alone or combined with the foreign mark. In most cases, foreign mark owners would not have used the Chinese equivalent mark outside China before the filing at the CTMO, so it is virtually impossible to establish that the Chinese equivalent mark was well known in China at the time of filing. So what is the answer? Follow the first-to-file principle literally and be the first to file at the CTMO.



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Original Article

China 10-Point Patent Checklist: Integrating patents into an overall business strategy for a Western manufacturing entity in China

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ABSTRACT The protection of intellectual property (IP) involved with manufactured goods comprises many aspects: Without even touching upon patents, these aspects include trade secrets and trademark protection, both very important in the classic protection of a pioneer manufacturer's product line and reputation. Yet it is well known that in China, Western companies have had challenges using trade secrets to safeguard IP. Trademark protection also has weaknesses, particularly as competitors often use Chinese marks that are very similar to the trademark – a situation that is difficult to control with typical trademark remedies. The China 10-Point Patent Checklist (Checklist) provides only starting points or guidelines for technology-based outsourcing operations – including biotechnology companies – doing business in China. The Checklist does not address comprehensive enforcement strategies such as deciding where to bring an action: in the United States (or Japan, Germany

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or another applicable importing country) under Western laws and Western patents, in China itself or in both countries.

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INTRODUCTION

The protection of intellectual property (IP) involved with manufactured goods comprises many aspects: Without even touching upon patents, these aspects include trade secrets and trademark protection, both very important in the classic protection of a pioneer manufacturer's product line and reputation. Yet it is well known that in China, Western companies have had challenges using trade secrets to safeguard IP, as it is extremely difficult to prove infringement in trade secret misappropriation cases under the current Chinese legal system. Trademark protection also has weaknesses, particularly because both domestic and foreign competitors often take advantage of China's first-to-file principle to disrupt foreign trademark owners' brand usage in China.

Protecting IP assets in China requires a combination of patents, trademarks and trade secrets. The Checklist provides only starting points or guidelines for technology-based outsourcing operations in China. The Checklist does not address comprehensive enforcement strategies such as deciding where to bring an action: in the United States (or Japan, Germany or another applicable importing country) under Western laws and Western patents, in China itself or in both countries.

Even today, with the well-known problem of outsourcing piracy, Western companies are doing little from a practical standpoint to safeguard their technology in China. A recent MIT Sloan Report¹ provides a useful general checklist for companies entering the Chinese market or coming to China with the principal goal of manufacturing products to distribute to other markets. Companies are told to be quick with patent registration; however, this is not so simple, as regular patents are granted

in China only after an examination that may take several years (a matter not uniquely Chinese, but a problem that faces companies both in the United States and many other countries). Companies are told to file for patents quickly because China is a first-to-file country; if a company is second to file, in line at the patent office after the first-to-file competitor, the company may still prevail if it can prove derivation as the originator of the product or technology, otherwise the secondto-file company would lose. Presumably the portfolio of important innovations already has patent protection in the West. This is problematic, however, if such patents have already been granted or the technology has been publicly disclosed.

The Checklist provides a set of practical ways to implement the goals suggested by the MIT Sloan Report.

1. A 'home-country' patent application should be filed in the United States (or any country) before the secrecy of a prototype product or new technology is made accessible to the public Classic American patent attorney thinking runs along the following lines: Since the United States is a 'first inventor' country and has a grace period of 1 year to file after public disclosure of an invention, there is no harm in waiting to patent until the end of the grace period. But most countries have no

grace period. This means that filing the American (or other first) application even one day after a public disclosure of the invention constitutes a total forfeiture of Chinese and most other foreign patent rights.

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China 10-Point Patent Checklist

2. A company must never rest on just 'the patent' keyed to the first filing, but must consider supplemental filings at every stage of product development

It is commonplace to file a single homecountry application with a complete disclosure of the first prototype of the invention. But technology often evolves through modifications: Each modification should be considered for inclusion in the patent portfolio. For modifications that occur within the first year of the home-country first filing, the simple, expedient method is to file a second (or third or fourth) application as a 'provisional application'² that includes this new disclosure. Then, on the first anniversary of the first filing, all disclosures are lumped together into a jumbo Patent Cooperation Treaty (PCT) application. Now, all the modifications also will be covered within the PCT application.

To simply attempt to add the modifications to the PCT application itself, without filing a second (or third or fourth) application means that these new modifications stand alone for patent priority purposes as of the PCT actual filing date, and not any earlier priority date. Patent applications typically have several different claims, so that claims entirely corresponding to the priority application will benefit from the earlier priority filing date, while claims first supported in the PCT application itself stand alone as of the PCT actual filing date. If there has been an intervening public disclosure of the new modification before the actual PCT filing date, then that intervening public disclosure will create an absolute forfeiture of any claim to the new modification.

3. Chinese (and other) foreign rights should be kept alive for at least 30 months through the expedient filing of a single PCT application within 1 year of the first home-country filing Foreign patent procedures in multiple countries can be very expensive, but major costs can be avoided for up to 30 months by filing a PCT application designating all important countries of the world, which are unique to each applicant. A PCT application, filed within 12 months of the home-country filing, allows a company to maintain its options for China – and other countries – without ever sending a single document overseas and without spending a penny on translation costs during this period.

The MIT Sloan Report suggests that '[t]he only solution for foreign companies is to file patents ... in China as soon as possible'. To better reach this goal, a more sophisticated approach is to utilise staged filings that take advantage of an intermediate PCT filing. In this case, the actual filing date of the PCT application is not so important; rather it is the priority date of the home-country filing or other first filing that is critical. (Of course, the PCT application must be filed within 12 months of the first filing or priority is lost.)

It has also been suggested that patents should be obtained in China, but this is not possible as there is an arduous examination process between the time of filing a patent application and its ultimate grant.

4. Product design should incorporate patent planning for added value In hindsight, it is easy to say that one should have sought a patent before the start of a China outsourcing programme. But if the existing situation involves no or minimal

patent protection, what can be done? If every detail of the product is open for copying, and no patent application was filed, it is simply too late for a patent-based remedy for that product. But products are constantly evolving: New features are added to the 'Second-Generation Widget'. This new product should be crafted in collaboration with patent experts to include features that are both novel (new before the filing date) and unobvious (obtained inventiveness over the prior art) versus the original 'Widget'. Then, this second-generation Widget is protected

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with a first filing in the same manner as any other new invention.

Obtaining patent protection for the new version does nothing to stop a competitor from making the old version, since it is in the public domain. Perhaps the new version is no better than the old one. So why patent the new version? If the company is concerned about an outsourcing factory running a clandestine midnight shift to overproduce the product and sell that overproduction through other channels, the second-generation patent meets the needs of the company because competitors are prohibited from making the second-generation products, which are covered by the second-generation patent.

5. Ornamental design features may provide further protection

Novel design features of the 'Second-Generation Widget' can be the basis for design protection, which is far easier to obtain than regular patent protection. In addition, design protection often is merely registered or minimally examined, resulting in very prompt protection, unlike a regular patent. First, file a home-country design application; within the next six months, file the Chinese and other parallel foreign design applications.

Critics of design protection dismiss this alternate form of protection because it is easy to create a different design to circumvent the design registration or patent. But the very point of a design registration or patent is to provide a tool against the exact or almost exact knockoff product. In such cases of infringement, the United States International Trade Commission may be used to enforce the American design patent against an importer. Japan has parallel protection available as well.

6. Special Chinese 'petty patent' protection is important

Unlike the United States, China has 'petty patent' protection via utility model patents.

This is a second form of patent that may be sought in addition to or in lieu of a regular patent.

The petty patent is registered and thus, by bypassing the normal, arduous patent examination process, is quickly granted.

The importance of the Chinese petty patent was manifested in the ongoing fight between the French Schneider, a pioneer manufacturer of certain low-voltage equipment, and the Chinese competitor Chint. The two were involved in actions in Europe. Chint surprised Schneider by obtaining petty patent protection that dominates the Schneider product, resulting in a damages award of more than \$44 million at the trial level. (Actions by Schneider to invalidate the petty patent as well as an appeal in the damages case are ongoing.)

7. Commercialised trade secret technology may be patented in China

It is axiomatic to American companies that if a trade secret has been commercialised for 1 year, patent protection is forfeited. This is true only insofar as domestic American patent rights are concerned. This is not true for Chinese patent protection: Trade secrets may thus be converted into a Chinese patent portfolio.

A Western company with a strong technological leadership position may often decide to forego patenting its highly sophisticated technology by relying upon strict factory security. Such trade secret protection has long been a viable option for many manufacturing companies because (a) it would be difficult for a third party to reverseengineer the product and (b) tight security could be relied upon to keep competitors from illegally obtaining company trade secrets.

Companies considering outsourcing in China should consider that trade secrets may be difficult to contain and that patent protection may be the better option. In this case, a provisional application should be

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filed in the United States for some of the trade secrets (those that can be readily reverse-engineered or otherwise revealed to competitors). Then, on the first anniversary of the provisional application, file a PCT (or simply a direct Chinese) application.

To be sure, obtaining a patent in China on a process or product that was formerly protected by trade secret will not provide rights that can be enforced in the United States, so Chinese enforcement must be relied upon to protect the American market. But if protecting the European and Japanese markets is important, then parallel process patents for Japan, Germany and other key European countries should be sought along with the Chinese patent: Importation into Japan or Europe of a product produced in China via a process patented in Japan or Europe will be the basis for a patent infringement action in Japan or Europe.

8. Chinese 18-month patent publications should be monitored

Chinese patent activity of Chinese competitors must be monitored to ensure that these competitors are not creating their own patent portfolio that could be used to block an American company from using its own technology.

Major patent offices of the world routinely publish all (or, in the United States, most) patent applications at or shortly after 18 months from the first filing.

Today, major companies monitor their home-country publications on the theory that most major inventions filed in, say, China also would be filed in the United States. Thus, finding a relevant US application published by a third party may point to parallel Chinese applications. But the flaw in this theory is that a Chinese company seeking protection only in China will have only a Chinese national application published in this manner (the publication would be produced, of course, in the Chinese language and only in China). Therefore, to supplement current patent-monitoring services that typically focus upon patent activity in the United States, Europe and Japan, a parallel search should be regularly conducted on Chinese-owned Chinese applications that do not have counterpart Western filings.

9. Prompt SIPO action is needed to deal with patent appropriation

As soon as it is discovered that a competitor has wrongfully filed a patent application to cover a company's product, prompt action must be taken at the State Intellectual Property Office (SIPO), the Chinese IP office.

As with even other first-to-file foreign countries, there is a 6-month grace period to commence an action against someone who wrongfully appropriates an invention and files a patent application in his name. Or, where it is discovered that a competitor has filed a patent application (or, even worse, gained a patent) on technology that the company has long practiced, steps such as filing an invalidation petition should be taken at the SIPO to invalidate the competitor's patent position.

10. Hands-on, patent-experienced Chinese business counsel is necessary

Only patent-experienced experts with a strong knowledge of the Chinese patent system can provide optimum counsel for managing Chinese patent problems. A Western company with a large patent staff would do well to send one of its experienced members – preferably someone with knowledge of Chinese customs and who can speak Mandarin – to Shanghai or Beijing for several years to gain hands-on experience.

All too often, Chinese matters are left in the hands of a Western expert with no China expertise or a Chinese expert with no patent expertise. Companies should be aware that 'IP' experts in China may have no specific patent experience; their specialty may be in (

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copyrights and trademarks, and there is little, if any, nexus between expertise in these fields and patent law.

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- 2. Since 8 June 1995, the United States Patent and Trademark Office (USPTO) has offered inventors the option of filing a provisional application for patent, which was designed to provide a lower-cost first patent filing in the United States. If applicants file a corresponding regular application within 12 months after the provisional application filing date, they are entitled to claim the earlier provisional application filing date as the date of filing the regular application.

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