

# LICENSING AND TECHNOLOGY TRANSFER TO CHINA: A ROADMAP

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## INTRODUCTION

**“FREE RIDING” PAST AND PRESENT.** A rapidly developing economy is hungry for the fruits of the intellectual labor of its more developed trading partners. It eagerly awaits their new products, and because the costs of respecting intellectual property rights are too high, the aggrieved creators are too far away, or cultural values do not make the protection of foreigners’ rights a high priority, the rapidly developing economy chooses to “free ride” on the investments of others in intellectual property.

If this is a familiar tale, the reader may be surprised to learn that we have been talking not about China or other contemporary emerging nations like India, but of the United States in the 19th century. In the words of America’s greatest copyright scholar, the late Melville Nimmer, “Like certain [Asian] locales about which American [producers of intellectual property] indignantly complain at present, the United States was a copyright piracy haven from the first [U.S.] copyright statute until . . . 1891. During that century, foreigners were utterly without rights under United States copyright law, and American publishers busied themselves bootlegging the works of Dickens, Trollope, Hugo, et al.”<sup>1</sup>

In current trade parlance, we might say that the United States was then a “free rider” on the investments of others in intellectual property. The roles have been reversed in the 21st century: the United States and other developed countries perhaps justifiably condemn “free riders” in the emerging economies for their less than rigorous protection of the developed countries’ intellectual property; developing countries counter with explanations of cultural differences and the difficulties of enforcement in societies unused to intellectual property protection or unable to pay the fully loaded costs of certain patented products such as pharmaceuticals.

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Among the countries most suspect in this regard is China. For several decades after the Communist Revolution of 1949, China remained to a large extent outside both the global trading economy and world intellectual property regimes. After a series of devastating policies, including the Great Leap Forward and the Cultural Revolution, China changed direction and began facing outward. In 1979, the Party Congress adopted Deng Xiao Ping's open door policy, and China now encourages foreign investment and technology transfer. The results have been remarkable, but there is still a significant lag between Western business norms and those of China. Moreover, China does not have its own tradition of intellectual property protection, a circumstance that it shares with other socialist regimes such as the former Soviet Union (although, in the case of China, for Confucian as well as Marxist-Leninist reasons) and with other less developed nations.

**CHINA JOINS THE WORLD ECONOMY.** At the time of the 1949 Revolution, China was a poor and relatively isolated country whose Gross Domestic Product (GDP; in purchasing power parity<sup>2</sup>) was some 16.5 percent that of the United States, according to the World Bank.<sup>3</sup> This has begun to change with astonishing rapidity. Today China's GDP is nearly 60 percent that of the United States. Indeed, China's current GDP is nearly three times that of Germany and is approaching twice that of Japan.<sup>4</sup>

In addition, China is no longer isolated. After some 15 years of negotiation with the other members of that organization, China joined the World Trade Organization (WTO) on December 11, 2001. This brought China much more fully into the global economic community and imposed certain intellectual property protection obligations on that country. In the words of the U.S. Trade Representative, China's accession to the WTO "was in many ways the culmination of two decades of economic reform that saw China move from a strict command economy to one in which market forces played an increasing role."<sup>5</sup> China's new ties to the rest of the world are indicated by the fact that by May 2000, nearly 350,000 companies had been set up in China by foreign investors from more than 180 countries and that total cumulative foreign direct investment in that country rose from a mere \$1.8 billion in 1983 to \$446.3 billion in 2002.<sup>6</sup>

Although widely known as a major exporter of goods (total foreign trade in 2004 reached \$1.1 trillion, making China the world's third largest exporter of goods),<sup>7</sup> China has also become one of the world's largest *consumers* of industrial materials (the world's biggest consumer of cement, steel, copper, tin, iron ore and coal, its second largest consumer of oil, aluminum, and lead, and its third largest consumer of nickel).

Moreover, China has a growing domestic consumer market, is becoming a significant investor in other countries, and is developing (or acquiring) its own global brands, with Lenovo's recent acquisition of IBM's personal computer business being perhaps the most widely known example.

Finally, it is a commonplace that China has a huge pool of low-cost labor, which now produces two-thirds of the world's DVD players, photocopiers, and

microwave ovens, 50 percent of its cameras, and a very large percentage of the world's clothing. What is less well known is that China has a large and rapidly growing pool of scientists and engineers who already do research and development work in China for companies like Microsoft, Cisco, IBM, and Siemens. However, perhaps the most startling statistic with respect to the size of China's admittedly still significantly undereducated workforce is that, according to the World Bank, *one employed person in four in the world is in China*.<sup>8</sup>

It is no surprise, therefore, that interest in technology transfer and the licensing of intellectual property to China is at a fever pitch.

Despite this interest, there are continuing concerns with the protection of intellectual property rights (IPRs) in China even with China's accession to the WTO and its acceptance of the WTO Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) as well as its adherence to the major international treaties and conventions on intellectual property.

Moreover, China is a major world power that does not always see eye to eye with either its Western or its Asian counterparts. Like most other countries in the world, it is subject to U.S. export controls over technology and other goods and services and has established its own regime for the regulation of technology imports and exports.

The purpose of this chapter is to guide the interested reader through the maze created by these factors and to enable persons interested in the transfer of technology and the licensing of intellectual property to China do so more practically and efficiently and with less risk.

## INTELLECTUAL PROPERTY PROTECTION AND ENFORCEMENT

### INTELLECTUAL PROPERTY RIGHTS HAVE LITTLE EXTRATERRITORIAL FORCE.

The first intellectual property-related difficulty for those wishing to transfer technology or license intellectual property to China involves the fact that IPRs generally have no "extraterritorial" force, i.e., they have no application outside the countries in which they have been enacted. By way of example, U.S. patents, trademarks, copyrights, and other forms of IPR protection do not protect such rights outside of the United States, its territories, or its possessions. The same is true of the intellectual property protection regimes of other countries—they generally have no force outside the countries in which they were promulgated.

**INTERNATIONAL TREATIES AND CONVENTIONS; TRADE REMEDIES.** It is easy to see how such a territorially based international regime could be an impediment to world trade, something that has been recognized in the developed world for more than a century. The traditional response was the promulgation of a series of multilateral, intellectual property-specific international conventions (treaties), which seek to provide at least a modicum of intellectual property protection to the owners of such rights outside their home countries and to facilitate the registration and recording of such rights.

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Among the most important of the international treaties currently in force are the Paris Convention for the Protection of Industrial Property (to which the United States acceded in 1887), the Berne Convention for the Protection of Literary and Artistic Works (to which the United States did not adhere until 1989), the Universal Copyright Convention, the Madrid Agreement for the International Registration of Trademarks (of which the United States is not a member), the Protocol to the Madrid Agreement (to which the United States acceded in 2003), and the Patent Cooperation Treaty (PCT), to which both the United States and China belong. The World Intellectual Property Organization (WIPO), an agency of the United Nations, administers these treaties and agreements.

With its acceptance of the TRIPS agreement and its accession to various international conventions, China has agreed to adhere to internationally accepted norms for the protection and enforcement of IPRs. This has required China to adopt legislation providing minimum standards of IPR protection and the enforcement of such rights in civil, criminal, administrative, and customs actions. TRIPS, for example, requires each of its signatories to protect the intellectual property rights of its fellow signatories by setting minimum standards of protection for copyrights and neighboring rights, trademarks, geographical indications, industrial designs, patents, integrated-circuit layout designs, and undisclosed (confidential) information. TRIPS also establishes minimum standards for the enforcement of IPRs in administrative and civil actions and, in regard to copyright piracy and trademark counterfeiting, in criminal actions and actions at the border. Finally, with very limited exceptions, TRIPS requires WTO members to provide “national” and “most favored nation” treatment to the nationals of other WTO members with respect to the protection and enforcement of their IPRs.

China’s obligations under TRIPS and the WTO to protect “inbound” IPRs therefore require it both (1) to enact legislation providing at least specified minimum protection for such rights, and (2) actually to enforce such protections in its courts and administrative agencies.

In the last 25 years, China has enacted a broad series of laws protecting IPRs, and although problems and gaps remain, the U.S. Trade Representative believes that “overall the legal changes made in China through 2003 were major improvements that moved the Chinese generally in line with international norms in most key areas.”<sup>9</sup> That China has done so in the short period of 25 years is a remarkable achievement.

Effective enforcement of these measures, however, has “not been achieved, and IPR infringement remains a serious problem.”<sup>10</sup> The next several sections describe the intellectual property protection regimes that China has adopted, the continuing problems of their enforcement, and the turn by the United States to the threat of trade sanctions to encourage China to protect the IPRs of U.S. persons more vigorously.

**CHINA'S INTELLECTUAL PROPERTY PROTECTION REGIMES. *Patent Protection in China.*** China's patent law was enacted in 1984 and has been amended twice since, with the most recent implementing regulations having been adopted in 2001 and amended in 2002. Like most of the rest of the world outside the United States, China employs a "first to file" rather than a "first to invent" system, and the duration of protection is now 20 years from filing for patents on inventions and 10 years for design patents and utility models (with a possible three-year extension). As noted above, China is a member of the Patent Cooperation Treaty, which streamlines the filing of patent applications in member countries. The holder of a foreign patent may therefore apply for a Chinese patent either directly (through China's State Intellectual Property Office [SIPO]) or via the Patent Cooperation Treaty, of which most countries are members. A foreign applicant without a residence or business establishment in China must, however, apply for protection with the assistance of a government-authorized patent agency. Under the current Patent Law, patentees have the exclusive right both (1) to sell patented goods in China and (2) to import patented goods into the People's Republic. In this regard, unauthorized importation constitutes an infringement, and the rights-holder may either sue in a Chinese court or request Chinese customs authorities to impound the infringing goods.

One important aspect of Chinese patent law is that a patent may be subject to a compulsory license in the event of a public emergency. Although we believe the Chinese government has not yet exercised this right, the SARS crisis prompted China to promulgate Regulations on Compulsory Licensing of Patents, reaffirming the government's right to do so in the appropriate circumstances. It should be noted that the rules governing such compulsory licenses contain what are intended to be certain procedural safeguards and the requirement that the patent holder be compensated, but the operation of these provisions has yet to be put to the test in a public emergency.

***Know-How and Trade Secrets Protection in China.*** Trade secrets and other confidential know-how and technological information are protected in China under that country's Contract Law and its Unfair Competition Law. Both affirm the enforceability of confidentiality and noncompetition provisions in licensing and technology agreements, provided they do not impose undue restrictions on the licensee or prevent the licensee from improving the licensed technology. Regulations issued by the State Administration of Industry and Commerce (SAIC) in 1995 provide a definition of "business secrets" and authorize legal or administrative action against third parties who have such secrets in their possession unlawfully. Remedies may include fines, confiscation of goods made with illegally obtained business secrets, and even the possible authorization of "self-help" measures. Moreover, the Technology Regulations reaffirm the enforceability of confidentiality and noncompetition provisions in cross-border licensing agreements.

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***Trademark and Trade Name Protection in China.*** Once again, China is a newcomer to the world of international trademark protection, although its history of protecting product identifiers may go back hundreds of years. The current trademark law was adopted in 1982 and has been revised twice. China's is a first-to-register rather than first-to-use regime, which opens the door to the possibility of mischief by the unscrupulous. However, a trademark registration may be voided if unfair means were used to obtain it, although this may take considerable time. It is therefore advisable to register one's marks as soon as possible; doing so will require the use of a government-authorized Chinese agent, although attorneys may help prepare the registration. Foreign application documents must be notarized and translated into Chinese. Because the United States and China are now both signatories to the Madrid Protocol, the benefits of that convention apply.

To comply with TRIPS, China has now extended its trademark protection beyond products to cover service marks and geographic indications of origin as well. Marks are protected by registration; a registration is valid for 10 years and may be renewed. Most distinctive identifiers can be registered, although sounds cannot. In this regard, Chinese law differs from that of the United States, where distinctive sounds that identify goods or services, such as the Microsoft Windows boot-up jingle, may be protectible.

China gives cross-industry and cross-class protection to "well-known" marks recognized as such by the Chinese Trademark Office provided they have been registered. "Well-known" marks that have not been registered in China are also protected, but they have no cross-industry or cross-class protection. In doing so, that Office will consider (1) how much the public knows about the mark, (2) how long it has been registered and used, (3) how much marketing has been done to promote the mark, and (4) whether it has already been protected as a "well-known" mark in either China or elsewhere.

Trade names are also protected under Chinese law, the details of such protection being set out in the Regulations on the Administration of Business Names; certain uses are prohibited under these regulations, such as the use by a Shanghai automobile maintenance company of the "Benz" trade name to suggest an affiliation with Daimler-Benz.

***Copyright Protection in China.*** As noted above, China has also adopted a modern copyright regime; the first such law was passed in 1990 and became effective in 1991 (and has been amended several times since). China has done so despite a Confucian tradition in which "stealing a book was [considered] an elegant offense"<sup>11</sup> and copying the works of others a tribute to them. Moreover, China's half-century of Marxism-Leninism, in which private property was looked on with disfavor, served further to undermine the concept of copyright protection. Nonetheless, China has adopted a copyright law and acceded to both the major international copyright conventions, such as the Berne Convention (which the United States only joined in 1989) and the Universal Copyright Convention, as well as the copyright provisions of TRIPS.

As is generally the case under international conventions such as Berne, registration is not a prerequisite to copyright protection in China, where protection is attached on. There is, however, a voluntary registration system that creates a presumption of ownership and is *prima facie* evidence of validity, defeating most conflicting evidence in the courts.

U.S. copyright rights-holders are protected by Chinese copyright law because both countries are members of the Berne Convention, and China adheres to the Berne Convention's rule of "national treatment" (nondiscrimination).

Among the classes of works protected by copyright in China is software, although engineering or business processes embodied in software are not protectible by copyright. Under China's current Copyright Law and the Regulations on the Protection of Computer Software, works of software created by individuals are protected for the life of the author plus 50 years. If the author is a business entity, such protection extends 50 years from first publication.

***Protection of Integrated Circuits in China.*** China protects integrated circuit designs under rules that came into effect on October 1, 2001 provided such designs have been registered with the State Intellectual Property Office. The details of such protection are set forth in the Regulations on the Protection of Integrated Circuit Designs and their implementing rules. The term of protection is 10 years, beginning on the earlier of first commercial use or the date of application for registration with SIPO.

**ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS AND THE THREAT OF TRADE SANCTIONS.** ***Enforcement Lags.*** The U.S. Trade Representative noted in his 2004 report to Congress on China's compliance with its WTO obligations that "[o]verall, China's efforts to bring its framework of laws, regulations and implementing rules into compliance with the TRIPS Agreement have been largely satisfactory, although some improvements still need to be made."<sup>12</sup>

Enforcement of IPRs in China is another matter. Effective IPR enforcement has not yet been achieved, and IPR infringement remains a serious problem. The sources of difficulty, according to the U.S. Trade Representative, are "a lack of coordination among China's government ministries and agencies, local protectionism and corruption, high thresholds for criminal prosecution, lack of training and weak punishments."<sup>13</sup> To this might be added the large amounts of money that can be made from the sale of goods based on stolen IPRs.

***Special 301: The Trade Weapon.*** China adopted its current intellectual property system as much in response to U.S. economic pressure as for other reasons. China's early forays into international trade in the 1980s, although successful, also exposed the inadequacy of its intellectual property laws and their lack of serious enforcement. The result was a series of confrontations between the two countries in which the United States resorted to the threat of tariffs against Chinese imports and China threatened reciprocal sanctions against the importation of U.S. commodities. In April 1991, for example, the U.S. Trade Representative

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initiated a “Special 301” investigation into Chinese practices, citing China as a “Priority Foreign Country,” the first step in imposing trade sanctions. At the time, China was the only major U.S. trading partner that did not “offer ... product patent protection for pharmaceuticals and other chemicals, [or] copyright protection for U.S. works.” This, the U.S. Trade Representative argued, resulted in large-scale piracy.<sup>14</sup>

Section 301 of the Trade Act of 1974, as amended (19 U.S.C. Section 2411), is the principal statutory authority under which the United States may impose trade sanctions against countries that maintain acts, policies, and practices that violate or deny U.S. rights or benefits under trade agreements or are unjustifiable, unreasonable, or discriminatory and burden or restrict U.S. commerce.

The “Special 301” provisions of the Trade Act, added in 1988, are designed to enhance the ability of the United States to negotiate improvements in foreign intellectual property protection. By April 30 of each calendar year, the U.S. Trade Representative is obligated to identify foreign countries that deny “adequate and effective” protection of IPRs or “fair and equitable market access” to U.S. persons relying on IPR protection. The Trade Representative must designate as “Priority Foreign Countries” those countries whose acts, policies, or practices are “the most onerous or egregious” and have the greatest adverse impact on relevant U.S. products and that have not entered into, or are not making significant progress in, negotiations to provide adequate and effective IPR protection.

The Trade Representative must normally self-initiate Section 301 investigations of Priority Foreign Countries within 30 days of identification, unless he or she determines that doing so would be detrimental to U.S. economic interests. If the investigation determines that the unfair trade practices the Act is designed to protect against are in fact being employed by the Priority Foreign Country, trade sanctions may thereafter be imposed.

The Special 301 procedure is a powerful weapon, far more powerful than a suit by an individual or group of individuals in an offending country’s courts under an international or bilateral intellectual property treaty.

***The 1991 Confrontation.*** As noted above, the U.S. Trade Representative initiated a Special 301 investigation of China in 1991. In response, the Chinese Ministry of Foreign Trade and Economic Cooperation (MOFTEC; the predecessor of the Ministry of Commerce [MOFCOM]) urged the United States to remove China from the Priority Foreign Country List, citing China’s recent adoption of new trademark, patent, and copyright laws, as well as China’s interest in joining the Berne Convention or the Universal Copyright Convention.<sup>15</sup>

After a series of intense negotiations, the United States and China failed to reach an agreement on these issues by the deadline set. However, rather than immediately imposing sanctions, the United States extended its investigation of Chinese IPR enforcement. It did, however, threaten China with the imposition of tariffs of 100 percent on a list of about \$1.5 billion worth of goods, later reduced to about \$750 million. China, for its part, threatened retaliatory duties on some



\$1.2 billion of U.S. commodities.<sup>16</sup> This was indeed trade war “brinkmanship.” Finally, some two months after the original deadline for these negotiations, the parties ended this first round of brinkmanship by entering into a Memorandum of Understanding (MOU), which ostensibly resolved their differences.

In return for a termination of the Special 301 investigation and an undertaking by the United States not to impose trade sanctions, China agreed to raise its then standards of IPR protection to international standards: It agreed to join the Berne Convention and the Geneva Convention on the Protection of Phonograms (for cassettes, CDs, and the like) and to protect computer programs as copyrightable “literary works” under Berne (the same classification they receive in the United States).

***The 1994 Confrontation.*** However, the resolution of tensions brought about by the MOU was short lived. Although China enacted the promised legislation, it seemed to do little to enforce its new laws. Tensions once again escalated just a few years later when China began exporting allegedly pirated products (such as CDs) by the tens of millions. Only two years after the 1992 MOU, the United States announced that China once again risked being listed as a “Priority Foreign Country” under Special 301. On June 30, 1994, China was so listed.

The United States estimated at the time that Chinese piracy was costing U.S. software companies some \$80 million a year and that sales of illegal CDs were costing U.S. rights-owners about \$400 million annually. Arguing that China’s enforcement of its intellectual property laws was “sporadic at best and virtually non-existent for copyrighted works,” the United States set a new deadline of December 31, 1994 to resolve matters.

Once again, the deadline passed without agreement, and the United States announced that it would impose up to 100 percent tariffs on selected goods from a list of Chinese products worth approximately \$2.8 billion in annual revenue for China. As the negotiations reached their final postdeadline stage, the U.S. Trade Representative announced that he had already ordered the automatic imposition of tariffs of 100 percent on over \$1.8 billion of imports of Chinese products if an acceptable compromise could not be reached by February 26, 1995. The Chinese, in turn, responded by announcing their own retaliatory tariffs on such U.S. exports as CDs and cigarettes.

Once more, the parties were able to avoid a trade war by reaching yet another agreement on the last day of the extended deadline and by China’s demonstration of its willingness to comply with at least some of its earlier promises. A few days before the extended deadline, Chinese authorities at last took action, which the United States had been demanding for months, raiding more than 25 factories producing pirated CDs for export and more than 40 distributors of pirated computer software.

***The 1996 Confrontation.*** Regrettably, this second agreement also fell short of its promise. Fourteen months later, the United States authorities remained unsatisfied with China’s enforcement of its intellectual property laws and once

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again named China a Priority Foreign Country under Special 301, on April 30, 1996. Two weeks later, the United States released a preliminary list of \$3 billion of Chinese goods from which \$2 billion would be sanctioned if China did not promptly improve its protection of IPRs. Once again, China threatened retaliation, and, once again, the parties reached an agreement at the eleventh hour.

**The Current Situation.** “Cut to the present”: Nearly ten years have passed, and the parties are still at odds on this issue, although trade between them has grown enormously. In 2004, the U.S. Trade Representative noted that addressing weak IPR protection and enforcement in China remains one of the U.S. government’s “top priorities.”<sup>17</sup> Rather than once again engaging in trade war brinksmanship, however, the parties managed to resolve their problems in the Joint Commission on Commerce and Trade (Joint Commission), which they had established in 1983 as a forum for high-level dialogue on bilateral trade issues. At its April 2004 meeting, China’s Vice Premier Wu Yi committed to the Joint Commission to reduce IPR infringements significantly throughout China in light of what the United States continues to assert are “rampant counterfeit and piracy problems that plague China’s domestic market, and China[’s] [having] become a leading exporter of counterfeit and pirated goods to the world.”<sup>18</sup> The United States has warned that it will monitor Chinese actions designed to meet its commitments to the Joint Commission and to additional, earlier bilateral agreements between the countries on intellectual property matters.<sup>19</sup>

Is the tale just told a continuing saga of *plus ça change*, or of China slowly adapting its legal systems, cultural presuppositions, and economic interests to full participation in the global economy? It is difficult to tell, although the fact that China is a far friendlier place for the protection of IPRs today than when it began its movement into the global economy seems clearly to be the case.

**Some Practical Suggestions in an Uncertain Environment.** Although it is likely that China’s enforcement of what are admittedly relatively new IPR protection regimes in a nascent and incomplete market economy are likely to improve, those interested in licensing intellectual property and/or transferring technology to China can take certain practical steps to protect themselves.

One way of doing so is to choose an appropriate business model; another is to choose appropriate governing law and arbitration or dispute resolution procedures. Still another is to ensure that only the appropriate level of technology (rather than the licensor’s “crown jewels”) is provided to the licensee.

In this regard, in certain cases it may be more sensible to establish a wholly owned subsidiary in China (when possible) and to transfer the rights and/or technology in question to it. This could provide greater control over the personnel in possession of the transferred technology and could enable the licensor to insist on the kinds of security and access procedures that are familiar in developed economies.

Registration of the transferor’s IPRs with Chinese customs can also be helpful. China’s obligations under TRIPS require a variety of border controls with respect to intellectual property export and import, and China Customs is now

empowered to inspect and ban infringing goods. The 2003 Regulations on Customs Protection of Intellectual Property provide for such registration, which is valid for 10 years. If the rights-holder believes that infringing goods may be about to enter or leave China, he may request China Customs to inspect such goods at the border. If infringing goods are found, they will be confiscated and the infringer fined.

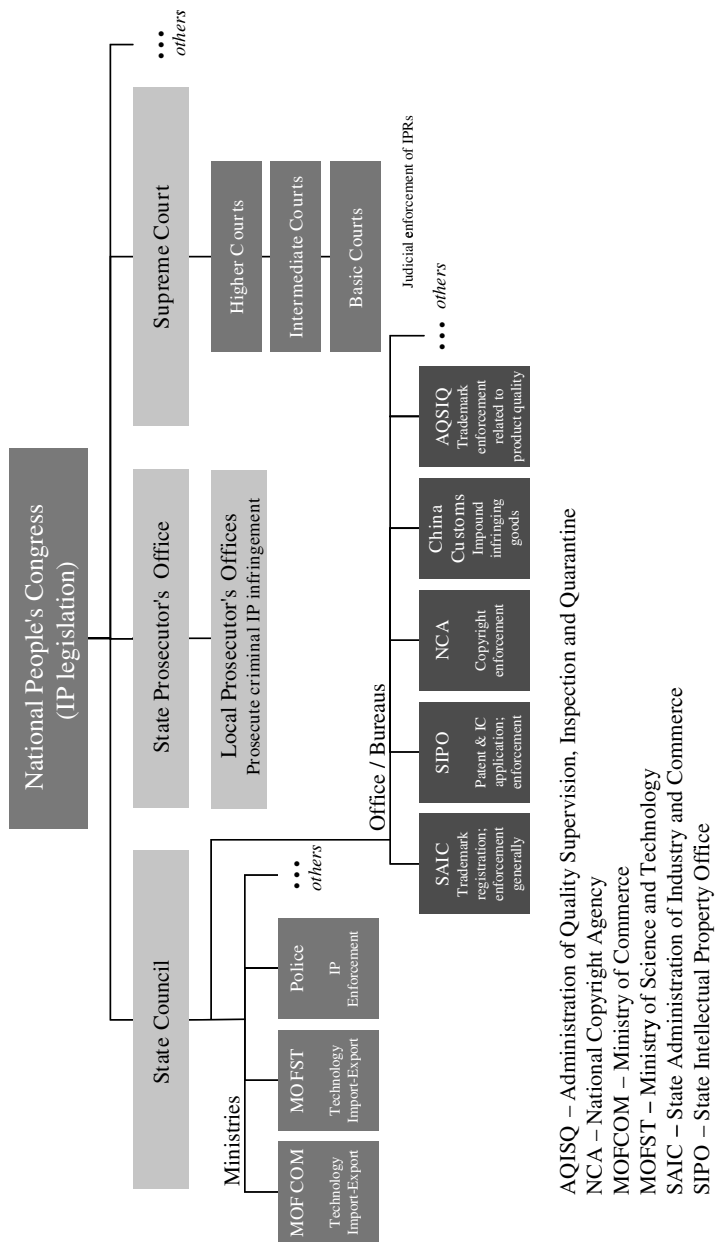
An appropriate choice of law may also be helpful. Chinese law permits the parties to a contract to select governing law if (1) at least one contracting party is a foreign party, (2) the legal relationship was created in a foreign country, or (3) the subject matter of the contract is located in a foreign country. In a license or technology agreement, if both parties are PRC entities (such as in an agreement between a wholly owned Chinese subsidiary of a U.S. company and another Chinese entity), Chinese law will govern the agreement, unless the agreement was negotiated and signed in the United States.

Finally, although it may seem self-evident, it may not be necessary for the licensor to transfer the entirety of a given technology to its Chinese licensee in order to achieve the desired commercial outcome. Careful consideration should therefore be given to just what needs to be provided to the licensee in order to achieve the parties' respective objectives and minimize the risks of intellectual property infringement while awaiting the emergence of a more dependable Chinese enforcement regime.

***Administrative and Judicial Enforcement of IPRs in China.*** If “push comes to shove,” however, additional measures may be necessary. In fulfilling its obligations under TRIPS, China has adopted a “dual-track” enforcement system for the protection of IPRs. The first track is administrative, under which a rights-holder may file a complaint of infringement with a designated administrative agency such as the ones listed below. The other involves recourse to the courts. For ease of reference, a chart listing the authorities discussed can be found in Exhibit 1.1.

#### ADMINISTRATIVE AGENCIES

- *Trademark*-related disputes are handled by the State Administration of Industry and Commerce (SAIC). In addition, the Administration for Quality Supervision, Inspection, and Quarantine (AQSIQ) also monitors product quality, handles infringements of registered trademarks if such infringements could give rise to inferior product quality, and issues administrative regulations with respect to the protection of indicators of geographic origin.
- *Unfair Trade Practices* are within the purview of the Fair Trade Bureau of SAIC, which handles disputes arising under the Unfair Competition Law (including disputes over know-how and trade secrets), investigates complaints of IPR violations, and destroys infringing goods.
- *Patent and Integrated Circuit* issues are handled at the administrative level by the Beijing Office of SIPO, the State Intellectual Property Office.



AQSIQ – Administration of Quality Supervision, Inspection and Quarantine  
 NCA – National Copyright Agency  
 MOFCOM – Ministry of Commerce  
 MOFST – Ministry of Science and Technology  
 SAIC – State Administration of Industry and Commerce  
 SIPO – State Intellectual Property Office

**EXHIBIT 1.1** ADMINISTRATIVE AND JUDICIAL AUTHORITIES IN CHINA

- *Copyright*-related issues are handled by the National Copyright Agency (NCA), which investigates software infringement, administers foreign-related copyright issues, develops foreign-related arbitration rules, and supervises local-level copyright agencies. However, because of staffing problems, the NCA often encourages complainants to pursue judicial remedies rather than employing its own procedures.

Other government agencies, such as the State Drug Administration and the Ministry of Culture, also play a role in the enforcement of China's IP laws: the former has jurisdiction over pharmaceutical counterfeiters, and the latter protects certain copyrighted works.

Regrettably, these administrative agencies cannot in most cases award damages to an injured rights-holder, although they may impose relatively modest fines on infringers and seize infringing goods. Although they typically provide a quicker and less expensive solution than judicial enforcement, their limited power to sanction wrongdoers often causes their sanctions to be treated by infringers as just another cost of doing business.

#### JUDICIAL ENFORCEMENT IN CHINA'S CIVIL COURTS

China has established specialized chambers in its civil courts throughout the country to deal with IPR matters and has empowered such courts to order money damages, injunctive relief, and other procedural relief in the case of infringement. Damages are generally computed on the basis of the rights-holder's losses caused by the illegal infringement. When such calculations are difficult, damages will be the infringer's unlawful gains. When this computation is also difficult, statutory damages may be awarded. These can range up to RMB 500,000 Yuan (about U.S. \$58,140 at this writing) in copyright and trademark cases and several times the royalty charged by the rights-holder to others in patent cases, depending on the circumstances.

Generally, judges in Beijing and Shanghai are considered competent and impartial. For example, the Haidian District Court in Beijing is well known for its sophisticated decisions involving software, high technology, and the Internet and e-commerce. Judges in other regions (particularly in those regions that have not yet been swept up in China's economic revolution) often lack both the necessary knowledge and impartiality to deal appropriately with IPR disputes. Local protectionism (or "home court advantage") is also an issue, although it is not unheard of in other countries as well.

One should therefore be very careful in choosing a court in which to bring suit and should pay particular attention to the choice of venue provisions in any license agreement. Under Chinese law, a choice of venue may be respected, but in the absence of an agreement as to venue, venue may lie where the defendant resides or the contract is to be performed. In the case of an infringement claim that arises in the absence of a license agreement, venue may be proper where the defendant resides, the infringement has occurred, the infringing goods are warehoused, or where they have been seized.

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### JUDICIAL ENFORCEMENT IN CHINA'S CRIMINAL COURTS

The criminal courts may be available for particularly egregious acts of infringement, such as large-scale commercial piracy and counterfeiting. Under current law, China's intellectual property administration authorities may transfer such cases to the police and criminal prosecution authorities for investigation. Although this is an available remedy (required under TRIPS), it is only rarely invoked, and its rare use remains a bone of contention between the United States and China.

**Arbitration and Mediation.** Given the difficulties and uncertainties just described, the parties to a technology transfer or intellectual property license agreement may wish to consider mediation or arbitration. This is especially the case since Chinese tradition values nonconfrontational solutions to problems whenever possible in order to maintain harmony.

Three primary options are available in China for mediation of a foreign-related dispute (one involving a non-Chinese party): (1) mediation conducted by a court after a lawsuit has been filed, (2) mediation conducted by an arbitral tribunal after an arbitration request has been made, and (3) privately administered mediation conducted under the auspices of a particular institution such as the Beijing Mediation Center.

The legal effects of a mediated settlement agreement depend on whether the mediation occurred within the context of a court program or arbitration proceeding and/or prior to any litigation or arbitration.

In a court-mediated settlement, the settlement agreement will be endorsed by the court and has virtually the same effect as a court judgment, although it is not subject to any appeals. If arrived at before an arbitral tribunal, the mediated agreement will take the form of an arbitral award. If a mediated settlement agreement is reached prior to any litigation or arbitration, the settlement is a contractual one, and failure of a party to comply gives rise to a claim for breach of contract.

Another alternative is arbitration, which (compared with litigation) has many features to recommend it to U.S. companies. The parties may choose their own arbitrators, thereby avoiding local judges who may lack expertise or impartiality. The parties may be represented by a broader range of persons, for example, a U.S. company may prefer to be represented by its U.S. attorneys, who may do so in an arbitration proceeding but may not give a legal opinion on Chinese law.

Moreover, arbitration proceedings (unlike litigation) may be kept confidential, a particularly sensitive matter in China, where litigation is often perceived of as being associated with criminal matters. However, perhaps the most important advantage of arbitration in this context is the enforceability of the arbitration award. Although China is not a party to any international conventions on the recognition and enforcement of foreign judgments, it has ratified the New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards (with some reservations not relevant to commercial disputes between a U.S. and Chinese party). Therefore arbitral awards rendered in the other signatory countries to the New York Convention are recognizable and enforceable by the Chinese courts.<sup>20</sup>

## U.S. AND CHINESE EXPORT AND IMPORT CONTROL REGULATIONS: "OUTBOUND" AND "INBOUND"

In addition to issues of intellectual property protection and the prevention of technological free-riding, cross-border licenses and technology transfers—particularly those involving military technologies—may also raise national security and related issues. Both the United States and China now have regulations in place designed to address these concerns.

As a result of the Cold War and its legacy, as well as concerns about global terrorism and nuclear proliferation, the United States has long had an elaborate system of export controls. More recently China has revised its own series of regulations in this regard. (These new regulations, which took effect on January 1, 2002, replaced earlier regulations dating back to 1985.)

Thus, U.S. and other companies wishing to transfer technology and/or license IPRs to China will need to understand both the U.S. and Chinese rules for exporting such items to China, what laws are in place in China to protect such transfers and licenses once made, and how likely such enforcement will be.

**U.S. EXPORT CONTROL REGULATIONS. *Introduction.*** Among the challenges of outbound U.S. technology transfer and intellectual property licensing is complying with United States export regulations. The U.S. Department of Commerce's Bureau of Industry and Security (BIS) is charged with implementing and enforcing a complex series of Export Administration Regulations (EAR), which appear at 15 Code of Federal Regulations Parts 730-774. These regulations govern the export and re-export of most commercial items, including those that have purely commercial uses and those that have both commercial uses and military or proliferation applications (so-called dual-use items).<sup>21</sup> As these regulations are exceedingly complex, it is recommended that qualified experts be consulted for all but the transfer of the most basic technology to China.

For the purposes of export control, any "item" sent from the United States to a foreign destination may be subject to export controls. "Items" include commodities, software, or technology, such as clothing, building materials, circuit boards, automotive parts, blueprints, design plans, retail software packages, and technical information.

Subject items leaving the United States only temporarily may also be subject to these regulations, as is the release of technology or source code subject to the EAR to a foreign national, even when that person is present in the United States. Such a transfer is "deemed" to be an export to the home country of the foreign national under the EAR and thus subject to those regulations.

The *means* by which an item is exported from the United States is irrelevant when determining the export license requirements to which it may be subject. By way of example, a tangible item may be sent by regular mail or by courier. A set of schematics can be sent to a foreign destination via fax, in digital form as an attachment to an e-mail message, or uploaded or downloaded from a Web site; controlled information can even be transmitted orally in the course of a telephone conversation.

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The good news, given the broad range of items subject to the EAR, is that a relatively small percentage of total U.S. exports and re-exports require an export license under this regime. This is the case because whether a license is required with respect to a particular item will depend on the item's (1) technical characteristics, (2) destination, (3) intended end-user, and (4) intended end use.

The Export Control Regulations state that “[f]or the People’s Republic of China, the general licensing policy is to approve applications, except that those items that would make a direct and significant contribution to electronic and anti-submarine warfare, intelligence gathering, power projection, and air superiority receive extended review or denial. Each application will be considered individually. Items may be approved even though they may contribute to Chinese military development or the end-user or end-use is military.”<sup>22</sup>

Because the exporting party must determine whether an export license is necessary, the following four questions must be carefully answered by persons wishing to transfer technology or license certain kinds of intellectual property abroad:

1. What is the item being exported?
2. Where is it being exported to?
3. Who will receive the item being exported?
4. What will the item be used for?

### *Determining Whether an Export License Is Required*

#### WHAT IS THE ITEM BEING EXPORTED? ITEM-BASED CONTROLS

The first step in determining whether an export license is required with respect to a particular item is to determine whether it has been classified by the BIS under its Export Control Classification (ECCN) scheme.

The ECCN is an alphanumeric code (e.g., 3A981) that describes a particular item, or type of item, and shows the controls applicable to that item. These codes (ECCNs) consist of an amalgam of numbers and letters from the Commerce Control Numerical List Categories (numbers) and from a list of Five Product Groups (letters). The Commerce Control List currently consists of the following ten identifying numbers:

#### *Commerce Control List Categories:*

- 0 = Nuclear materials, facilities, and equipment (and miscellaneous items)
- 1 = Materials, Chemicals, Microorganisms, and Toxins
- 2 = Materials Processing
- 3 = Electronics
- 4 = Computers
- 5 = Telecommunications and Information Security
- 6 = Sensors and Lasers



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7 = Navigation and Avionics

8 = Marine

9 = Propulsion Systems, Space Vehicles, and Related Equipment

Once the appropriate Commerce Control List Category number has been determined, the next step is to determine into which of the following (alphabetic) Five Product Groups the item falls:

- A.** Systems, Equipment, and Components
- B.** Test, Inspection, and Production Equipment
- C.** Material
- D.** Software
- E.** Technology

By way of example, assume you wish to export polygraph equipment to be used by law enforcement agencies. Step one is to find the category on the Commerce Control List into which polygraph equipment falls—in this case, it is Category 3 (electronics). The next step is to determine into which of the Five Product Groups it falls—in this case it is Group A (systems, equipment, and components). Thus, polygraph equipment is in Category 3A. Category 3A will contain a list of items falling within that category. In this example, the item is 3A981 (see Supplement No. 1 to Part 774 of the EAR). The listing under 3A981 will specify what license requirements may apply and the reasons for such control, which of a set of license exceptions may be available, and other information.

If an item is under the jurisdiction of the EAR and is not listed on the Commerce Control List, it is designated as EAR99. These items generally consist of low-technology consumer goods and do not require a license in many situations. Exceptions to this rule may apply if the item to be exported is to an embargoed country, to an end-user of concern, or in support of a prohibited end-use. In such cases, a license may be required.

**WHERE IS THE ITEM BEING EXPORTED TO? COUNTRY-BASED CONTROLS**

This element of the analysis will vary from country to country. The most restricted destinations are embargoed countries and those designated as supporting terrorist activities, including Cuba, Iran, and North Korea, among others. Although a relatively small percentage of all U.S. exports and re-exports require a BIS license, virtually *all* exports and many re-exports to embargoed destinations and countries designated as supporting terrorist activities require a license. (See Part 746 of the EAR for a list of the embargoed destinations and certain additional controls imposed by the Office of Foreign Assets Control of the Treasury Department.)

Once the ECCN number has been determined for the item of interest (i.e., it has been classified), the next step is to determine whether an export license is necessary based on the "reasons for control" of the item and its country of

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ultimate destination. Among the listed reasons for control of various items and the abbreviations by which they are known are “National Security (NS),” “Anti-Terrorism (AT),” “Crime Control (CC),” “Chemical and Biological Weapons (CB),” “Nuclear Nonproliferation (NP),” and so on.

The next step is to compare the item’s ECCN with the EAR’s Commerce Country Chart (which is found at Supplement No. 1 to Part 738). Taken together, the Commerce Country Chart and an item’s ECCN define the items subject to export control based solely on the technical parameters of the item and the country of its ultimate destination.

The EAR at Supplement No. 1 to Part 738 contain a matrix in which ECCNs, countries, and reasons for control are set forth in a grid. For a given item, if there is an “X” in the cell based on the reasons for control of the item and the country of destination, a license is required, unless a specific “License Exception” (discussed below) is available. If there is no “X” in the control code column of the matrix under the ECCN and country of destination, no export license will be necessary *unless the item is being exported to an end-user or for an end-use of concern*. This is discussed more fully below.

If one examines the matrix, one finds a variety of “X”s in the China row, indicating that licenses for the export of such technology to China may be necessary absent one of the “License Exceptions” set forth in the regulations. Among the reasons for the control of such exports to China given are the control of chemical and biological weapons and missile technology, concerns over nuclear proliferation, national security, missile technology, and regional stability. (To put these rules in their proper perspective, it may be helpful to note that a similar number of “X”s appear in the row for Israel, for example, although Israel has been a U.S. ally for decades.)

### WHO WILL RECEIVE THE ITEM BEING EXPORTED? END-USERS OF CONCERN

Certain individuals and organizations are prohibited from receiving U.S. exports, and others may only receive goods if they have been licensed (even with respect to items that would not otherwise require a license by virtue of their location on the ECCN and Commerce Country Chart matrix or an EAR99 designation). There are four classes of such individuals and organizations: (1) those appearing on the so-called Entity List, (2) those appearing on a list of Specially Designated Nationals and Blocked Persons maintained by the Department of Treasury’s Office of Foreign Assets Control, (3) those appearing on a Denied Persons List consisting of U.S. and non-U.S. persons whose export privileges have been denied by BIS, and (4) those appearing on a so-called Unverified List, which consists of firms for which BIS was unable to complete an end-use check.

### WHAT WILL THE ITEM BE USED FOR? USES OF CONCERN

The final variable in determining whether and to what extent the EARs apply to a given item is to determine the uses to which the item will be put after export. Some end-uses are prohibited entirely, whereas others may require a license. An item that would by its nature otherwise not be subject to control may be prohibited if its intended use is forbidden. Thus, one may not export otherwise innocent

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items to certain entities involved in the proliferation of weapons of mass destruction (e.g., nuclear, biological, chemical) and the missiles to deliver them, without specific authorization. More information on prohibited end-uses may be found at Part 744 of the EAR.

SUMMARY

Thus, United States export control is based on:

1. What the item being exported is.
2. Where it is being exported to.
3. To whom it is being exported.
4. What it will be used for.

*Applying the Rules*

NO LICENSE REQUIRED (NLR)

Most exports from the United States do not require a license and may therefore be exported under the designation No License Required (NLR). Except in those relatively few transactions in which a license requirement applies because the item's destination is subject to embargo or because of a proliferation concern with end-use or end-user, no license is required when:

1. The item to be exported is not on the CCL (Commerce Control List), i.e., it is classified as EAR99; or
2. The item is on the CCL but there is no "X" in the box on the Country Chart matrix under the chart's country row and reason for control column.

In each of these cases, a person wishing to export such an item would enter the designation "NLR" on his export documents.

LICENSE EXCEPTION

Even in those cases in which a license might otherwise be required for export of a given item, a license exception may be available for that item. The list of License Exceptions, and the conditions for their use, may be found in Part 740 of the EAR.

If the item in question is eligible for a license exception, a person wishing to export such an item would enter the designation of that license exception (e.g., "LVS," "GBS," "TMP") on his export documents.

LICENSE REQUIRED

In those cases in which a license for export is required, application must be made to the BIS for an export license. If the application is approved, a license number and an expiration date to be used on the export documents will be issued by the BIS, such licenses generally being valid for two years.

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**CHINA'S REGULATIONS FOR TECHNOLOGY IMPORTS AND EXPORTS.** *The Foreign Trade Law of 2004.* Under prior Chinese law, the rights to import and export were special rights and were limited to a small number of Chinese companies and foreign-invested enterprises (FIEs). A registration system has now replaced the approval regime, and China's Foreign Trade Law of 2004 permits both Chinese and foreign firms and individuals to import and export, subject to a registration regime and certain technology import and export regulations. With few exceptions, any individual or company whose business is legally registered with the State Administration of Industry and Commerce is eligible to engage in foreign trade after registering with a local office of the Ministry of Commerce (MOFCOM). Such filings can even be completed electronically on MOFCOM's Web site (<http://iecms.ec.com.cn/iecms/index.jsp>).

**Technology Import and Export Regulations.** China's regulations focus on both technology *imports* and technology *exports*. Under the Regulations for the Administration of Technology Import and Export, effective January 1, 2002 (Technology Regulations), technologies that are "inbound" to China from other countries are divided into (1) those that may be freely imported (Freely Imported Technologies), (2) technologies whose importation is restricted (Restricted Technologies), and (3) technologies whose importation is prohibited (Prohibited Technologies).

Contracts involving Restricted Technologies require government approval to be effective and may be subject to substantive review by Chinese government authorities. Contracts involving Freely Imported Technologies need only be registered—rather than approved—and such registration is not necessary for their effectiveness. The registration process is speedier and less burdensome than the approval process, and contracts involving Freely Imported Technologies will not be subject to substantive government review. The Technology Regulations suggest that technology transfer agreements as a class will be treated as involving Freely Imported Technologies by default, unless otherwise provided by law.

**Catalog of Technologies Prohibited from Import and Export.** Prohibited and restricted technologies are listed in a Catalog of Technologies Prohibited and Restricted from Import (the Import Catalog) and a Catalog of Technologies Prohibited and Restricted from Export (the Export Catalog), each of which provides important guidelines. A review of this information should be a preliminary due diligence matter before negotiations on technology transfer and licensing begin.

If a specific technology does not appear in the Import Catalog, it may be "freely" transferred into China. "Freely," in this regard, means that no government approval is required for a technology transfer agreement (such as a patent license, an assignment of patent or of a patent application, or an expert services contract); such agreements are effective upon their execution. However, such agreements must still be registered with MOFCOM, or one of its local offices,

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depending on the scale and importance of the transaction. Although failing to register the agreement will not void the contract, doing so is necessary for the importer/exporter to complete the necessary administrative procedures required by China's foreign currency exchange administration, banks, and tax and customs authorities. Without registration, completing the necessary procedures with these authorities will not be possible. Thus, registration, although not a formal requirement, is a practical one.

If a technology appears on the list of restricted technologies in the Import Catalog, it cannot be imported into China without an import license from MOFCOM. Application for such a license can be completed in two steps: (1) obtaining a preliminary approval (which permits one to enter into the technology transfer agreement), and (2) obtaining the import license itself (which has the same legal effect as the registration of a contract to import freely tradable technology). The importer and exporter apply to MOFCOM for a preliminary approval to import the technology in question. MOFCOM and the Ministry of Science and Technology together examine the application and determine whether to approve or deny it. If approved, a Certificate of Preliminary Approval is issued, and the parties may enter into their technology transfer agreement. Once they do so, they then submit a copy of the agreement to MOFCOM and will receive the import license itself, the second review presumably being to make certain that the terms of the agreement conform to the information in the application for preliminary approval.

***Technology Transfers as Capital Contributions.*** If the technology transfer is designed to be a capital contribution to a foreign-invested entity (FIE), the transferor may make such a contribution, but MOFCOM's rules limit the value of such contributions in kind to 20 percent of total capital contributions to the FIE. However, local governments (which are eager to attract foreign investment) may be willing to allow foreign investors to receive a larger share of capital for their technology contributions to a foreign-invested entity.

A final note: Importing "prohibited" technology may give rise to both administrative and criminal sanctions, so a careful examination of the Import Catalog is highly recommended for those wishing to license or otherwise transfer technology to China.

***Exporting Technology from China.*** A brief note on *exporting* technology from China seems advisable despite our focus in this chapter on U.S.-outbound transactions. China prohibits or restricts the export of certain technologies, particularly those with potential military applications, such as nuclear technology, military-civilian dual-use technology, conventional arms (including missiles), chemical and biological weapons, and satellite communications. Other restricted technologies include encryption and computer network security technology, and (tellingly) Chinese herb prescriptions. Non-Chinese companies wishing to establish R&D facilities in China in any of these areas with the goal of re-exporting the results of such research, or companies interested in trading non-Chinese

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technology for restricted or prohibited Chinese technologies, would do well to exercise appropriate due diligence at an early part of the process.

The Technology Import Regulations also contain a number of other important provisions, including (1) the requirement that the foreign licensor provide certain warranties regarding the technology, (2) a rule providing that improvements to the technology rest with the party making such improvements, and (3) the prohibition of certain “tying-like” arrangements in which the licensee is required to buy from the licensor, and other similar rules.

### CONCLUDING THOUGHTS

As the pace of globalization quickens, one can imagine a variety of both benign and less comforting scenarios for the context in which technology transfer and intellectual property licensing to China will take place. Among these might be the continued growth of interdependence between the economies of the United States and China accompanied by a more realistic appreciation by each of the other’s related domestic concerns. Other possibilities include greater strain. Based on the histories of other countries that have gone through the transition from centrally planned to market economies, China is likely to face significant domestic strains as growing wealth creates new centers of economic power alongside those now in place. Although such new constituencies are likely to be friendly to the continued liberalization of China’s economic policies and China’s efforts to achieve greater protection for IPRs, other groups perhaps left behind by China’s rapid growth may seek to slow (and even reverse) the pace of progress. Moreover, China’s growing economic power is already beginning to be felt politically and militarily, particularly in Asia. What all of this suggests is that technology transfer and intellectual property licensing to China is likely to be both an enormously profitable and greatly challenging enterprise in the years ahead and that rigorous and systematic planning is sure to be required for a successful endeavor.

### Endnotes

1. M. Nimmer and D. Nimmer, *Nimmer on Copyright* (2003), 17-12–17-13. Newark, New Jersey: Lexis/Nexis—Matthew Bender.
2. Because of the differences in price levels for various goods and services among countries, comparing their respective gross domestic products is not a straightforward matter. To arrive at a more meaningful set of comparisons, the “purchasing power parity” approach involves the comparison of prices of a basket of comparable and representative goods and services across countries. This basket includes some 3,000 items and covers the entire range of final goods and services (consumption goods and services, government services, equipment goods, and construction projects) that make up the GDP. By comparing the respective pricing of these baskets of goods, more meaningful comparisons of GDP can be made.
3. Peter Rhodes, *Riding the Dragon*, Presentation to Shareholders’ Retreat of Heller Ehrman LLP, Phoenix, Arizona, March 13, 2005.

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4. World Development Indicators Database, World Bank, September 2004, available at [www.worldbank.org/data/databytopic/GDP\\_ppp.pdf](http://www.worldbank.org/data/databytopic/GDP_ppp.pdf) (last viewed March 24, 2005).
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7. "China's Foreign Trade to Grow 30%," China Daily, December 31, 2004, available at [www.chinadaily.com.cn/english/doc/2004-12/31/content\\_404975.htm](http://www.chinadaily.com.cn/english/doc/2004-12/31/content_404975.htm) (last viewed March 31, 2005).
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11. See William Alford, *To Steal a Book Is an Elegant Offense: Intellectual Property Law in Chinese Civilization* (Stanford, CA: Stanford University Press, 1997), in which the author quotes this aphorism of "unknown provenance."
12. United States Trade Representative, *2004 Report to Congress on China's WTO Compliance*, December 11, 2004, 59.
13. *Ibid.*, 62.
14. Office of the United States Trade Representative, *Fact Sheet: Special 301 on Intellectual Property*, Federal News Service, April 26, 1991.
15. Gregory S. Feder, "Enforcement of Intellectual Property Rights in China," *Virginia Journal of International Law* 37 (1996): 223, 240.
16. *Ibid.*
17. U.S. Trade Representative, *2004 Special 301 Report*, 1.
18. *Ibid.*, 11.
19. *Ibid.*, 13.
20. For a complete discussion of these issues, see Joseph T. McLaughlin, Kathleen M. Scanlon, and Xichun (Catherine) Pan, *Commercial Dispute Resolution in Mainland China* (2005), available from the senior author at [jmclaughlin@hewm.com](mailto:jmclaughlin@hewm.com).
21. Although the Bureau of Industry and Security is in charge of most export controls and is the agency that promulgates the EAR, it should be noted that several departments and two commissions also have export control responsibilities (the State Department oversees defense articles and services, the Justice Department oversees most controlled drug issues, including related chemicals and precursor agents, the Department of Health and Human Services via the Food and Drug Administration manages the export of other drugs, biologics, medical devices, and investigational drugs, and the Department of Energy and the Nuclear Regulatory Commission oversee nuclear materials and technology). 15 C.F.R. Part 730, Suppl. No. 3.
22. 15 C.F.R. Section 742.4(b)(7).

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