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Legal Updates

* this article is contributed by Foley & Lardner LLP

Legal Updates

1. Interpreting the Revised Draft of the Anti-unfair Competition Law: Commercial Bribery (Authors: David TANG, Min ZHU)

On February 25, 2016, the Legislative Affairs Office of the State Council promulgated the *Anti-Unfair Competition Law of the People's Republic of China (Revised Draft for Comment)* ("**Revised Draft**"). This is the first time that China has revised the *Anti-Unfair Competition Law of the People's Republic of China* ("**Existing Law**"), which has been in effect for 23 years. The Existing Law was promulgated in 1993 during China's transition from a planned economy to a market economy. With the deepening of reforms, many provisions of the Existing Law have been incompatible with the continued development of the market economy. The SAIC started to revise the Existing Law in 2003 and the revision has been in progress since that time. The Revised Draft revises 30 of the 33 articles of the Existing Law, removes 7 articles and adds 9 new articles, with 35 articles in total. One highlight of the Revised Draft is that it revises the provisions relating to commercial bribery.

Comparing the Provisions

The comparison of relevant provisions before and after the revision is shown in the following chart.

Existing Law and Regulations	Revised Draft
Article 8 of the Existing Law: Business operators shall not resort to bribery, by offering money or goods or by any other means, in selling or purchasing commodities. Business operators that offer off-the-book rebates in secret to another party, a unit or an individual, shall be deemed and punished as offering bribes; and any unit or individual that accepts off-the-book rebates in secret shall be deemed and punished as taking bribes. Business operators may, in selling or purchasing commodities, expressly allow a discount to the other party and pay a commission to a middleman. Business operators that give discounts to another party and pay commissions to a middleman must truthfully make such entries in their accounts. Business operators that accept discounts or	Article 7: Business operators shall not engage in commercial bribery as follows: (1) by being in the public service and seeking, or by relying upon public services to seek, unit, departmental, or personal economic benefits; (2) between business operators, by paying economic benefits that have not been truthfully recorded in the contracts and accounting documents; (3) by offering or promising to offer economic benefits to third parties to influence transactions which damage the legitimate rights and interests of other business operators or consumers. Commercial bribery refers to the acts of a business operator that induce others to seek business opportunities or competitive advantages for the business operator, such as offering or promising to

commissions must also truthfully make such entries in their accounts. Article 2 of the *Interim Provisions of the State Administration for Industry and Commerce on the Prohibition of Commercial Bribery* ("Interim Provisions"): Commercial bribery shall mean a business operator's act of bribing a counterparty organization or individual with property or by other means for the purposes of selling or purchasing commodities.	offer economic benefits to counterparties or to third parties that may influence transactions. Offering or promising to offer economic benefits is regarded as offering a commercial bribe, accepting or agreeing to accept economic benefits is regarded as accepting a commercial bribe. Acts of commercial bribery committed by employees who seek business opportunities or competitive advantages on behalf of a business operator shall be regarded as acts of that business operator. If there is evidence that an employee accepted bribes contrary to the business operator's interests, such acts shall not be regarded as acts of the business operator.
Article 22 of the Existing Law: A business operator that resorts to bribery by offering money or goods or by any other means in selling or purchasing commodities, and, if the case constitutes a crime, shall be investigated for criminal liability according to law; if the case does not constitute a crime, the supervision and inspection department may impose a fine of not less than 10,000 yuan but not more than 200,000 yuan in light of the circumstances and confiscate the illegal earnings, if any.	Article 20: Where a business operator violates Article 7 hereunder, the supervision and inspection authorities shall order the illegal activities to cease and impose a fine of not less than 10% but not more than 30% of the illegal business revenue in light of the circumstances; where the act constitutes a crime, criminal liability shall be prosecuted in accordance with the law

Interpreting the Revised Draft

a. Indirectly bribing "third parties" determined to be illegal

In the Existing Law and Interim Provisions, the provisions on commercial bribery merely mention "counterpart organizations or individuals." In the Revised Draft, however, the subjects accepting bribes not only include "counterparties" in the conventional sense, but also include "third parties that may influence transactions", such as supervisors or relatives of the counterparty, managers of the parent or affiliated company and the public officials who have the decision-making authority over the transaction.

In practice, according to some responses issued by the SAIC and the Supreme Court，some acts of business operators that induce and influence the third parties in business transactions have been

determined to be commercial bribery. For example, a hospital that gave "referral fees" or "prescription fees" to doctors from other hospitals and induced the doctors to recommend that patients undergo CT scans at the hospital, a shopping mall that gave "personnel fees" or "parking fees" to travel agencies and tour guides to induce them to organize group tours to the shopping mall, a beer brewery that recycled beer bottle caps from bartenders and offered cash to induce the bartenders to recommend the brewery's products to consumers, and an insurance company that offered "insurance handling fees" to schools and in order to induce the schools to sell such insurance to their students. The Revised Draft reaffirms these determinations in legislative form.

It is worth noting that what matters is that the act is likely to influence the transaction rather than the realization of economic benefits. The new legislation broadens the definition of commercial bribery and gives administrative authorities greater discretion in enforcement.

b. Blaming the "acts of employees" no longer a defense for employers

In judicial practice, many business operators being prosecuted for commercial bribery offenses attempted to avoid punishment by claiming that the acts of commercial bribery were due to the individual actions of their employees. The Revised Draft follows the principle of presumptive fault liability in the civil law field and specifies that acts of commercial bribery committed by employees who seek business opportunities or competitive advantages on behalf of a business operator shall be regarded as acts of that business operator. If there is evidence that an employee accepts bribes contrary to the business operator's interests, such acts shall not be regarded as acts of the business operator. In this case, a business operator has to produce evidence in support of its claim that the employee's acts were contrary to its interests, which challenges the business operator's internal compliance systems. We expect that this revision will also encourage business operators to develop internal compliance policies and employee training.

c. "Promising to offer economic benefits" also constitutes commercial bribery

It is stipulated in the Existing Law that business operators that actually offer or accept commercial bribes should be held legally responsible. However, the Existing Law does not stipulate any consequences for business operators that promise to or propose to offer commercial bribes. In the Revised Draft, the methods of conducting commercial bribery are defined as "offering or promising to offer economic benefits". The Revised Draft uses identifying principles similar to the U.S. Foreign Corrupt Practices Act for reference and defines the acts of "promising to offer economic benefits" as commercial bribery, which broadens the scope of commercial bribery.

Pursuant to the Revised Draft, some controversial business models that were not explicitly addressed by law may now be regarded as acts of commercial bribery. The widely used "Donate Equipment + Sell Consumables/ Raw Materials" business model in the food and drug industries will probably be determined to be an act of commercial bribery pursuant to the Revised Draft. Such examples of this business model include a medical equipment company that donates medical devices to a hospital in return for agreements to exclusively buy the chemical reagents needed to

run the machines, or a food company that donates food-processing devices to a retailer in return for agreements to exclusively buy food ingredients.

d. It is risky if economic benefits "have not been truthfully recorded"

In practice, the contracts prepared by many companies are complete (especially the standard form of business terms and contracts). However, the actual enforcement of a contract may not be completely in line with its terms. In the accounting books, situations may exist in which the account headings are inconsistent with the actual business operations. The inconsistency between the facts and contract terms (or accounting documents) may be caused by mistake, but it is also possible that such inconsistencies are intentional. For example, a pharmaceutical product purchaser clearly records business discounts into its accounts, but the discounts are not used to reduce the purchase cost. The purchaser records the discounts in "other receivables," "other earnings" or under some other heading that is for a different purpose. In this case, the purchaser may be suspected of receiving kickbacks instead of receiving commercial discounts. Such activity has already been determined to be commercial bribery by the AIC in practice and the Revised Draft reaffirms this administrative determination.

Pursuant to the Revised Draft, if the economic benefits offered by business operators, including discounts, commissions and kickbacks, have not been truthfully recorded in the contracts and accounting documents, such benefits will probably be determined to be commercial bribes. This provision is intended to distinguish commercial bribery from normal business discounts, and to crack down on the illegal activity of business operators that conceal their acts of commercial bribery by using contract terms or account headings. The Revised Draft objectively increases the risks to business operators.

e. Fines proportionate to the extent of fault

Pursuant to the Existing Law, the administrative penalties for commercial bribery mainly include fines and the confiscation of illegal income. The Revised Draft removes the penalty of confiscating illegal income and adjusts the fine amount from "not less than CNY 10,000, but not more than CNY 200,000" as stipulated by the Existing Law to "not less than 10% but not more than 30% of the illegal business revenue." The amount of the fine imposed is proportionate to the illegal business revenue, which is not a fixed amount. This stipulation reflects the administrative enforcement principle that the amount of the fine should equal the extent of fault.

The main reason that the Revised Draft removes confiscating illegal business revenue as a penalty is because, in practice, it is difficult for administrative authorities to calculate and prove the precise amount of illegal business revenue from commercial bribery. In some situations，while the illegal business revenue does exist, the amount is unable to be calculated. It will be convenient for law enforcement authorities to use "illegal business income" amount as the cardinal number, and this stipulation will help to reduce disputes to a large extent. Besides this point, the provision is in line with the legislative trends reflected in the *Food Safety Law* and the *Regulations on the Supervision*

and Administration of Medical Devices, which recently changed the language from "illegal income" to "value of goods."

Regulatory Trends

Although the Revised Draft is still at the consultation stage, it already reflects the trends that China has emphasized in the supervision and enforcement in the area of anti-unfair competition law. In December 2015, the National Symposium on the Anti-unfair Competition Law Cases convened. The Symposium pointed out that, under new situations, the AIC and market supervision departments should enhance the overall awareness, investigate and handle the major cases, which impair market order and strengthen market supervision in key areas.

In recent years, China has strengthened administrative supervision in key industries that are prone to commercial bribery. By last year, the *Circular on Printing and Distributing the Provisions on the Establishment of Adverse Records of Commercial Bribery in the Medicine Purchase and Sales Industry* has been implemented in dozens of provinces and cities. The adverse record system may be used in other key industries prone to commercial bribery in the future. Hence, we recommend companies in such industries to pay more attention to the risks of commercial bribery, develop internal control policies, adjust business practices, conduct internal employee trainings and take measures to avoid these legal risks as early as possible.

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2. Breakthrough – First Company with a VIE-Structured Controlling Shareholder Listed on NEEQ (Author: Domestic Capital Markets Team)

Introduction

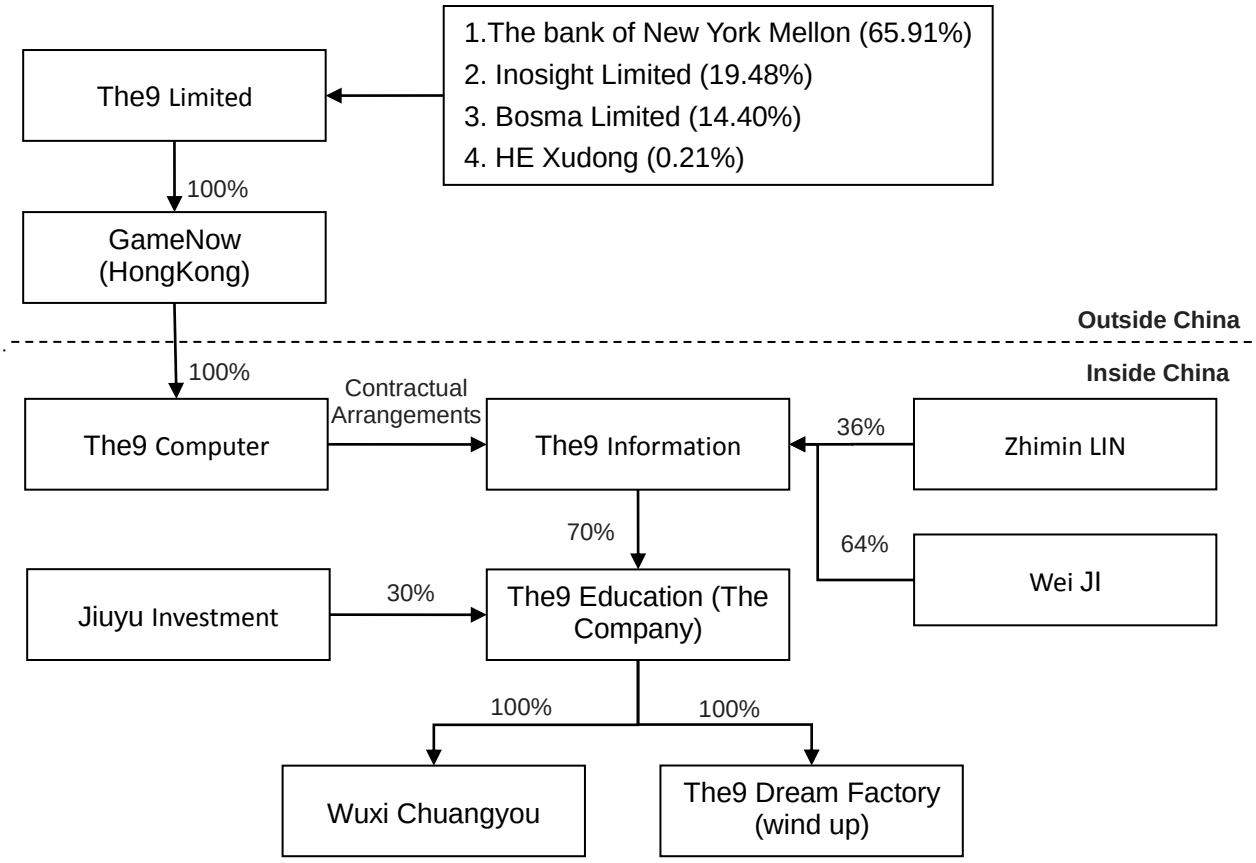
According to public information, Shanghai The9 Education Technology Co., Ltd. ("**The9 Education**" or the "**Company**") was recently approved to be listed on the National Equities Exchange and Quotations ("**NEEQ**"). The Company and its subsidiaries mainly engage in "the creation of game application-oriented techniques, the provision of technical services, non-academic/non-certificate software application development and technical skills training, consulting and other related professional services in the mobile internet field." In this case, the Company disclosed that its controlling shareholder was subject to the provisions of VIE agreements, which resulted in the Company being the first to list on the NEEQ while having disclosed that its controlling shareholder was an entity subject to a VIE structure. Before this, Beijing LEFTBRAIN Network Technology Co., Ltd. had also disclosed that 58 Co., Ltd. (the "**58 Limited**"), which became its controlling shareholder after a share issuance, was subject to VIE control structure.

General Information

According to The9 Education's Public Transfer Statement disclosure for the NEEQ listing, the Company's controlling shareholder, Shanghai The9 Information Technology Co., Ltd. ("**The9 Information**"), is subject to VIE arrangements, under which The9 Information acts as a domestic operating company. The actual controller of The9 Information is The9 Limited, which is listed on the NASDAQ exchange. Thus, The9 Education became the first company to successfully list on NEEQ after clearly disclosing that its controlling shareholder was subject to VIE control.

The9 Information's Disclosure of its VIE Structure

According to the Company's disclosures in its Public Transfer Statement and Legal Opinion for this listing, the Company's equity structure and the VIE structure controlling The9 Information at the time of listing are as below:



Analysis

When answering whether The9 Information, which is subject to VIE structure control, had a clearly defined equity structure and satisfied legal and regulatory conditions for NEEQ listing, the main content of the intermediary agency's response included:

a. The shareholders of the Company had not executed any controlling agreements with respect to the shareholders' rights with any third party.

b. Each shareholder of the Company (including follow-on shareholders) exercises shareholder rights according to its respective shareholding ratio in deciding on major matters of the Company. The exercise of shareholder rights within the Company is not subject to the restrictions of the VIE structure.

c. The Company's equity structure is clearly defined. The Company has never entered into any specific arrangements with any third party for the transfer of the business revenues of the Company and has always kept its business revenues within the Company. The shareholders of the Company (including follow-on shareholders) are entitled to receive the profits of the Company in proportion to their respective shareholding ratio.

d. Given that the Company is not the only holding subsidiary of The9 Information, the revenue and profit of the Company will not significantly impact The9 Information.

e. Neither the controlling agreements for the creation of the VIE structure nor the subsequent agreements for altering the structure refer to the Company as the main party. The Company is not bound by the provisions of the relevant VIE agreements.

f. The creation of the VIE structure as well as the financing activities of the offshore entities have been carried out in accordance with the relevant laws and regulations. Although the foreign exchange registration for the return investments of natural persons was slightly flawed, this did not constitute a substantive legal obstacle for the listing.

g. The business conducted by the Company and its subsidiaries does not belong to the education industry, which is restricted to prohibited from foreign investment according to the *Catalogue for the Guidance of Foreign Investment Industries (Revised in 2015).*

The9 Education set a precedent by successfully listing on NEEQ while clearly disclosing that one of its shareholders, in this case the controlling shareholder, was an operating company controlled under contractual arrangements. Although this case is of little guiding significance to companies whose main business belongs to industries that are restricted or prohibited from foreign investment, it still causes us to consider whether more foreign-controlled red-chip companies in non-restricted industries will be approved for NEEQ listing in the future.

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3. Medical Devices: Protection of IP Rights in the United States - What Chinese Companies Should Know (Author: Jeffrey H. Greene from Foley & Lardner LLP)

For Chinese companies to launch medical device products in the United States market, the secret to safeguarding product intellectual property lies in a good understanding of all available options.

Choosing which type of intellectual property (IP) protection is the most suited for your medical device is not always easy, especially when a device is eligible for more than one type of protection. This article discusses the types of IP protection that are generally applicable to medical devices in the United States. Knowing which types are available, appropriate, and most beneficial—as well as knowing the timing and method of making the right choices—is crucial to understanding how to protect your devices. We explore these issues through the following questions:

• What types of IP protection may be available for medical devices?

• What are the general advantages and disadvantages of each type?

• Which types of IP protection can be used together, either successively or simultaneously, and which may be mutually exclusive?

Types of IP Protection

The following section explains the five different forms of IP protection and their application to a medical device. Medical devices can be of various types, such as imaging devices, sensors, analytical systems, clinical treatment devices, implantable products, and prostheses, to name a few. In each of these categories it is important to achieve optimum protection as well as the type of protection best suited for different categories of devices.

a. Protection by Trademark

A trademark is any word, symbol, design, smell, or sound, or any combination thereof, that identifies the source of a product or service. Registrability should be seen as a hierarchy, with "inherently distinctive" marks at one end, "generic" marks at the other end, and "descriptive" marks with acquired distinctiveness somewhere in the middle.[1] The more distinctive a mark is, the greater the scope of protection it will receive.

Trademarks can apply to medical devices in several ways. First, the name of the device, as well as any symbol or slogan used on or in connection with the product that identifies the source of the product, may be protectable. Second, the “look and feel,” or aesthetic design of the device, may be protectable as a particular type of trademark called “trade dress.” In the United States, unlike in China where registration is generally required, trademark rights arise out of mere use of the

[1] 15 U.S.C. § 1127.2.; *see Abercrombie & Fitch v. Hunting World, Inc.*, 537 F.2d 4 (2d Cir. 1976).

trademark in commerce. Additional benefits accrue through registration of a trademark with the United States Patent and Trademark Office.

Example: The "brand name" for a device may be entitled to immediate trademark protection if it identifies the source of the product and is not a generic or descriptive term. Similarly, if the device bears a symbol or logo that accompanies the name, that symbol or logo may also be protectable as a trademark.

Using trademark law as a form of IP protection presents several advantages. For instance, trademark rights may exist perpetually so long as the trademark is being used properly, is licensed only under appropriate quality controls, is enforced against infringers, and is monitored for misuse.[2] This is the case even if the product design changes over time, which can be a key difference from patent, copyright, or even trade dress protection. In addition, the costs of obtaining trademark protection may be low relative to other forms of IP protection, such as utility patents. However, there are some disadvantages to be aware of. For instance, it may take substantial time and investment to gain recognition of your name, slogan, or symbol to acquire sufficient source-identifying power. Under the use-based system in the United States, in order to perfect those rights, the trademark must be properly used and "attached" to the goods.

Protection by Trade Dress: While trade dress is often perceived as a unique form of IP protection, trade dress is really a form of trademark protection. Trade dress has been defined as "the total image of a product, including such features as 'size, shape, color, or color combinations, texture, graphics, or even particular sales techniques.'"[3] As with trademarks, trade dress must have sufficient source-identifying power to be protected. Additionally, trade dress protection is only granted for nonfunctional aspects of the design.[4]

Example: If the shape or color of a device does not serve a utilitarian or functional purpose and is purely aesthetic, such features may be protectable as trade dress.

As with word and logo marks, trade dress protection may last indefinitely. Further, deciding to change the external, visible product design may limit or even extinguish trade dress protection by altering the distinctive appearance that consumers use to identify the source. In addition, care must be given when licensing trade dress rights to third parties, alone or bundled with other rights (such as patents), so as to not limit, or even extinguish the trade dress rights.

b. Protection by Patents/Utility Patents/Design Patents

In the United States, utility patents and design are protected as patent rights, and are both applicable to medical devices.

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2 *See Kohler Co. v. Moen, Inc.*, 12 F.3d 632, 637 (7th Cir. 1993).

3 Roulo v. Russ Berrie & Co., 886 F.2d 931, 935 (7th Cir. 1989) (internal citation omitted).

4 Wal-Mart Stores, Inc. v. Samara Bros., Inc., 529 U.S. 205 (2000).

Utility Patents: A utility patent may be sought on any "new and useful process, machine, manufacture, or composition of matter."[5] An invention may be protected with a utility patent if it is novel, non-obvious, and useful.[6] Subject to some exceptions, the term of a utility patent in the United States is 20 years from the earliest U.S. filing date of any nonprovisional patent application to which the patent application claims priority.[7] While obtaining a utility patent can be expensive, the benefits of filing are numerous. Issued patents enjoy a presumption of validity in legal proceedings and patents can be a major source of income, as the rights to use the technology may be licensed to competitors or be kept for competitive advantage.

Design Patents: Design patents protect the novel ornamental features of a patented design. Like a utility patent, a design patent allows the patentee to exclude others from using the patented aspect of the product. While the utility patent term is 20 years from the filing date, the term for a design patent is 14 years from the date of issue.[8]

Example: A medical imaging device may have various features and design aspects that can be protected with patents. Utility patents may protect the new features provided by the software and hardware design. Design patents may protect the user interface and the exterior configuration.

c. Protection by Copyright

Although many people think of copyright law only as a tool for protecting artistic works such as paintings, songs, and books, copyright protection can be sought for a wider range of intellectual property. Copyright protection may be granted to "original works of authorship fixed in any tangible medium of expression."[9] Thus, so long as a work is original, is fixed in a tangible medium ("sufficiently permanent or stable to permit it to be perceived, reproduced, or otherwise communicated"), and consists of copyrightable subject matter, it should be eligible for copyright protection.[10] A copyright only protects the expression or embodiment of an idea rather than the idea itself.

Example: A medical imaging device may have several aspects that may be protected under copyright law. Such aspects include the software used to run the device, artistic designs applied to the exterior housing, and the look and feel of the user interface.

There is a fine line, however, between "applied arts," which are copyrightable, and useful "industrial design," which is not copyrightable.[11] Courts have held that the design of a useful article, like a medical device, can be protected by copyright only to the extent that its artistic features can be

5 35 U.S.C. § 101.
6 35 U.S.C. §§ 101-103.
7 35 U.S.C. § 154(a)(2).
8 35 U.S.C. § 173.
9 17 U.S.C. § 102(a).
10 See Williams Elecs., Inc. v. Artic Int'l, Inc., 685 F.2d 870, 874 (3d Cir. 1982).
11 17 U.S.C. § 101.

identified separately from and exist independently of the useful aspects of the item.[12] This idea is also best explained by means of an illustration:

Example: If an implantable medical device were designed with curves configured to secure the device in place in the body, and the same curves were also artistically attractive, such features may not qualify for copyright protection. The reasoning here is that the design aspects for which copyright protection is sought, i.e., the curves of the device, serve a useful function. These artistic features cannot be separately identified or exist independently of the useful aspects of the item.

If all of the criteria for copyright protection are met, copyrights confer some important protections on their owners. First, the owner of a copyright possesses the exclusive right to reproduce, distribute, and perform or display the copyrighted work, as well as create derivative works based on the copyrighted work.[13] Second, U.S. copyright protection lasts for the life of the author, plus 70 years in the case of a single author.

d. Trade Secret Protection

As the name suggests, trade secret law protects information that derives economic value from being "kept secret." Under the Uniform Trade Secrets Act, trade secrets are different from trademarks, patents, and other forms of IP in that, by their very nature, they are not disclosed to the public. Trade secrets may include source code, business plans, customer lists, marketing strategies, and process-related inventions.

Examples: The maker of a device could keep as a trade secret the method for creating a particular alloy that is used in an implantable device. The manufacturer could also keep the list of doctor and hospital clients as a trade secret.

Trade secrets can exist indefinitely, so long as the information remains secret. One difficulty with relying on trade secrets, however, is that they can be difficult to monitor for improper use. Further, there is no recourse if the trade secret is lawfully reverse-engineered. Moreover, owners of trade secrets who suspect that their trade secrets have been misused or misappropriated may be reluctant to pursue litigation out of fear of having the secret information divulged. Unlike a patent or trademark registration, which carries a presumption of validity, a prima facie case of trade secret theft requires the plaintiff to demonstrate that it possessed confidential information and made reasonable efforts to retain its secrecy.[14]

Comparison Chart

12 Brandir Int'l, Inc. v. Cascade Pac. Lumber Co., 834 F.2d 1142 (2d Cir. 1987).
13 17 U.S.C. § 106.
14 Learning Curve Toys, Inc. v. Playwood Toys, Inc., 342 F.3d 714 (7th Cir. 2003).

It is possible that the different features of a product could meet the requirements for several, or perhaps all, of the types of IP protection discussed above. The question then becomes which form or forms will be most advantageous to protect the assets in question.

The good news: courts have consistently held that "a product's different qualities can be protected simultaneously, or successively, by more than one of the statutory means for protection of intellectual property."[15] This means that upholding trademark protection on product configuration is not necessarily equivalent to improperly granting perpetual patent protection to the configuration.

For example, in a case involving Mogen David Wine Corp.,[16] the court held that trademark rights can extend after the patent term expires because the two forms of protection "exist independently. . . under different law and for different reasons." In the *Yardley* case, the court held that a design patent and copyright could apply simultaneously because "Congress has not provided that an author-inventor must elect between securing a copyright or securing a design patent."[17] Thus, it is possible, and perhaps advisable, to attempt to secure different forms of protection for the same asset. Table I compares the different types of IP protection.

[Table 1] Comparison Chart

Type of Protection	What Does It Protect?	Advantages	Disadvantages	Compatible With
Trademark	• Words • Symbols • Devices • Sounds • Scents • Trade dress	• Low cost • Potentially perpetual	• Varying degrees of protection based on distinctiveness • May only exclude other marks that create consumer confusion	• Trade dress • Copyright • Design patents • Utility patents
Trade Dress	• Nonfunctional features that are distinctive • Color • Shape • Packaging	• Low cost • Potentially perpetual	• Varying degrees of protection based on distinctiveness • May only exclude other trade dress that creates consumer confusion	• Design patents • Copyright • Trademark • Trade secret • Not utility patents (for same features)
Patent	• New and	• Strong	• Limited term	• Trademark

15 Kohler , 12 F.3d at 638.
16 In re Mogen David Wine Corp., 328 F.2d 925, 930 (C.C.P.A. 1964).
17 In re Yardley, 493 F.2d 1389, 1394 (C.C.P.A. 1974).

Type of Protection	What Does It Protect?	Advantages	Disadvantages	Compatible With
	non-obvious (and useful, for utility patents)	protection • Presumption of validity • Easily licensed	• Expensive	• Copyright • Not trade dress (for same features) • Not trade secret
Copyright	• Original, tangible expression	• Lasts over 70 years • Low cost • Easily licensed	• Difficult to obtain copyright protection for useful articles • Expression of the idea is protected, not the idea itself	• Trademark • Trade dress • Patent • Trade secret
Trade Secret	• "Secret" information that provides economic value	• Perpetual protection if kept secret • Low to no cost	• Once discovered by legitimate means, protection is lost • Licensing negates secrecy	• Trademark • Trade dress • Copyright • Not utility patents (for same feature)

As the preceding chart highlights, many types of IP protection may be used together without conflict if applied to different aspects of a medical device. For example, a utility patent could cover the invention itself while trademark law could be used to protect the name of the product. The more interesting question is: when can two or more different IP protections be simultaneously or successively sought? For instance:

Trade dress may be incompatible with utility patents. An expired utility patent may be evidence that the feature is functional and therefore not eligible for trade dress protection. Choosing to include ornamental aspects of product design in a utility patent may foreclose potentially perpetual trade dress protection.

Design patent and trade dress protection may often be pursued for the same feature. One strategy to leverage both forms of protection is to secure a design patent and then use the period of exclusivity to build a record of consumer recognition in support of trade dress protection.

Utility patent and trade secret protection for the same feature are incompatible. Deciding which to pursue can be a critical business determination. For instance, if a third party discovers your unpatented secret through legitimate means and patents it, you could lose your rights to use the technology you developed. However, if the invention is not easily reverse-engineered, then trade secret protection may be more appropriate.

Advice: Carefully Consider Your IP Goals

Ultimately, the question of which type of IP protection is best for your device cannot be determined by simply looking at the pros and cons of each type. Careful, strategic consideration, in view of near- and long-term goals, should be given to factors such as available capital, the value of the device and its intended longevity, foreseeable design changes, and even the intention to license the device or the underlying IP. For example, if the device is in a field where technology changes rapidly and brand recognition provides competitive advantages, then trademark protection for the name and logo may be advisable. If a competitive advantage is derived from the device's technology, then a utility patent should be considered. If the device incorporates a technological process that is not easily reverse-engineered and can be kept secret, then trade secret protection may suffice. If the device has a unique and recognizable appearance, then its design may be important to protect through trade dress, copyright, and design patent protection.

Choosing one form of IP protection does not necessarily preclude using another form of protection concurrently or successively. In order to optimize protection of medical devices, a layered approach may be appropriate, such as seeking a strong protection in the short to middle term from patents while seeking longer term protection through copyrights and trademarks.

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4. Branded Drug Pricing Mechanism Reform and the Elimination of Monopoly Profits (Authors: Chen MA, Da SHI)

In October 2015, the CPC Central Committee and the State Council issued Several Opinions on Advancing Pricing Mechanism Reform. As the Opinions clearly state, China will generally lift price controls over all goods and services in competitive sectors by 2017. In the pharmaceutical field, pricing mechanism reform has always been both widely watched and controversial. In May 2015, seven ministries jointly issued Opinions on Promoting Drug Pricing Reform, abolishing the separate pricing mechanism for branded drugs. This started a new round of drug pricing reform.

Branded drugs were granted the privilege of separate pricing in 2010, pursuant to provisions issued by the former State Planning Commission. The price of branded drugs is much higher than that of generic drugs, which is called "Super National Treatment." However, is separate pricing the only reason for the substantial difference in price? The answer may be "no." Admittedly, there is still a gap between the quality and efficacy of some generic drugs and branded drugs. Besides this, it is noteworthy that doctors have no incentive to choose reasonably priced generic drugs since they do not need to pay for medicines, and choosing generic drugs may also expose doctors to the risk of

patient complaints. Thus, the development of generic drugs has been impeded and the pharmaceutical manufacturers have had to lower the generic drug prices close to the cost of production in order to survive in the market.

To solve this pricing problem in the pharmaceutical field, a series of measures have been taken:

On the supply side, State Food and Drug Administration initiated a project to research methods of evaluating the quality and efficacy equivalence of generic drugs. Once implemented, most of the generic drugs of poor quality and efficacy will be eliminated and the high-quality generic drugs will be more accepted since they have been proven qualified.

On the demand side, the General Office of the State Council issued guidance to implement comprehensive trial reforms in urban public hospitals. One of the reforms is to eliminate hospital commissions for selling drugs. These measures can cut off the profit chain between hospitals and drug prices to a certain extent. Another reform is the introduction of a centralized purchasing mechanism, which is conducive to further splitting the profit chain, thus improving the situation on the demand side.

Overseas experience shows that patent drug manufacturers may avoid or reduce the huge profit losses caused by the patent cliff by way of "product hopping." This refers to when the patent for an older drug is going to expire, the drug manufacturer may take soft or hard measures to force consumers to switch to a new patent drug before a generic version of the older patent drug becomes available. Patent drug manufacturers may force product hopping on consumers by leveraging their market dominance, which may impede generic competition and violate competition laws. Although there has not yet been a product hopping case reported in China, product hopping may likely emerge once the price reform succeeds and generic drugs gain more competitive advantage in the China market. The PRC Anti-monopoly Law needs to be prepared to meet the challenges posed by product hopping. Two of the most prominent challenges for regulatory authorities may be proving market dominance, and the methodology of viewing the product hopping behavior as a whole rather than in parts.

Important Announcement

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