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WEBINAR FEATURE

Avoid On-Sale Bar by Filing Early Both in the United States and China Post-Helsinn

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Under 35 U.S.C. § 102(a) of the Leahy-Smith America Invents Act (AIA), an inventor is precluded from obtaining a patent if the invention is “on sale” before the effective filing date. In *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, the U.S. Supreme Court further clarified that an invention is considered on sale even if the details of the invention have not been made available to the public.¹ This article examines the “on-sale bar” standard in China and how U.S. businesses should apply the *Helsinn* decision to direct their activities in China, and why they are encouraged to file early patent applications in both the United States and China.

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[A Comparative Discussion of U.S. and Chinese On-Sale and Public Use Bars to Patentability](#)

The *Helsinn* Decision

AIA 35 U.S.C. § 102(a) precludes an inventor from obtaining a patent if the invention is “on sale” before the effective filing date. Specifically, the “on-sale bar” provision states: “[a] person shall be entitled to a patent unless . . . the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.”²

The on-sale bar applies when the product is determined to be “the subject of a commercial offer for sale” and when the invention is “ready for patenting.” Ready for patenting could be proved by evidence of “reduction to practice” or “drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention,” regardless of whether the details of the invention had been disclosed.³ On the other hand, if the subject matter is derived from the inventor or a joint inventor, a one-year grace period is in play.⁴

Since the enactment of the AIA, however, it remained unclear to many practitioners what the catchall phrase “otherwise available to the public” encompassed. For example, could a confidential sale agreement between an inventor and a third party trigger the on-sale bar provision and hence invalidate the patent?

On January 22, 2019, the U.S. Supreme Court addressed this question head-on in a unanimous decision, declaring that the addition of the catchall phrase “otherwise available to the public” does not change the meaning of “on sale” as it was used before the AIA, and that a confidential sale agreement between an inventor and a third party still triggers the on-sale bar provision under the AIA.⁵

In September 2000, after Helsinn’s announcement that it would begin clinical trials of a 0.25 mg and a 0.75 mg dose of palonosetron product⁶ named Aloxi[®] and sought marketing partners for this product, Helsinn entered into a license agreement and a supply and purchase agreement with its marketing partner MGI Pharma Inc. The license agreement authorized MGI to distribute, promote, market, and sell the 0.25 mg and 0.75 mg doses of palonosetron in the United States. Under the supply and purchase agreement, MGI agreed to exclusively purchase from Helsinn any palonosetron product approved by the FDA. While both agreements included dosage formulation information, neither the subsequent press release nor the 8-K filing disclosed such information. On January 30, 2003, nearly two years after the agreements, Helsinn filed a provisional patent application covering the 0.25 mg and 0.75 mg doses of palonosetron. Subsequently, in May 2013, Helsinn filed its fourth patent application under the AIA, claiming the priority date to the 2003 provisional application. The patent was later issued and covered a fixed dose of 0.25 mg of palonosetron in a 5 ml solution.

In 2011, Teva Pharmaceutical Industries Ltd. and its American affiliate, Teva Pharmaceuticals USA Inc. (collectively, Teva), applied for approval from the FDA to market a generic 0.25 mg palonosetron product. Helsinn sued Teva for infringement. In its defense, Teva claimed that Helsinn’s patent was invalid because the product was “on sale” more than one year before Helsinn’s 2003 provisional application. Helsinn argued that the patents in suit were valid because its agreements with MGI did not disclose the actual formulation and hence could not constitute “on sale” as a matter of fact.

The district court sided with Helsinn, holding that the on-sale bar “requires that the sale or offer for sale make the claimed invention available to the public.”⁷ On appeal, the Federal Circuit disagreed with the district court and held that the on-sale bar was triggered even if the details of the invention were not disclosed.⁸ In its view, to be consistent with pre-AIA case law, Congress, in enacting the AIA, never intended to add “a requirement that the details of the invention be disclosed in the terms of sale.”⁹ Helsinn subsequently filed, and the Supreme Court granted, a writ of certiorari.

In affirming the Federal Circuit’s decision, the Supreme Court held that its pre-AIA interpretation of the on-sale bar controlled, and that the AIA did not alter the meaning of “on sale” in the on-sale bar. According to the Court, the Federal Circuit has long held that the “on sale” provision has a well-settled meaning that “‘secret sales’ can invalidate a patent.”¹⁰ “A commercial sale to a third party who is required to keep the invention confidential may place the invention ‘on sale’” under the AIA as under the pre-AIA statute, and “[t]he addition of a broad catchall phrase [‘otherwise available to the public’]” does not change the “well-settled meaning when the AIA was enacted.”¹¹ Accordingly, “a *sale or offer of sale* need not make an invention available to the public. . . . [Our] cases focus on whether the invention had been sold, not whether the details of the invention had been made available to the public or whether the sale itself had been publicly disclosed.”¹² By saying this, the Court clarified, for the first time, that a secret sale triggers the on-sale bar under the AIA. Additionally, the Court confirmed that the on-sale bar is also triggered by an “offer of sale.”

After almost eight years of litigation, Helsinn not only lost its issued patent but also is faced with mounting attorney fees and litigation costs. What’s worse is that it is doomed to lose its future sales because those generic drug applicants do not have to wait until the patent expires to introduce their generics to the market, as competitors are entitled to mass produce the generic drugs the following day after the Supreme Court’s decision—on average, branded drugs are predicted to lose their market share by up to 84 percent in the first year after the entry of generic drugs.¹³ Furthermore, after the *Helsinn* decision, companies’ longtime practice of negotiating confidential sales covered by either confidential or nondisclosure agreements

may nevertheless risk invalidating a granted patent or being prevented from obtaining a patent, essentially affecting pharmaceutical companies' early stage licensing and acquisition deals, worth more than \$157 billion over the last decade.¹⁴ Naturally, inventors are advised to file an application before engaging in the sale, as inventors who decide to sell before filing a patent application now run a risk of not being able to obtain a patent when the invention is "ready for patenting." And there is no need for the inventors to be worried about the problems arising from early filing, for applicant inventors can still request a suspension of action, defer examination under 37 C.F.R. section 1.103, and/or make amendments after filing. If a commercial agreement is necessary before the filing, it is advisable that counsel be involved to review whether the agreement constitutes a "sale" or "offer for sale." For a corporate applicant, it also means that its sales team now must ensure that the invention they are going to promote has been filed in the patent office.

"On Sale" and "Offer for Sale" under China's Patent Law

On the other side of the world, post-*Helsinn*, U.S. entities doing business in China inevitably are confronted with additional inquiries: Does the *Helsinn* decision affect U.S. business practice in China, such as signing a sales agreement with a Chinese entity before filing? Is there an on-sale bar in China, and can a secret sale also invalidate a patent in China? How does China apply *Helsinn* to its practices to comply with Chinese laws? Before turning to these questions, we will first discuss the interpretation of "sale" under China's Patent Law.

Under China's Patent Law, there coexist two kinds of "sale" behaviors, namely, "on sale" and "offering for sale." First promulgated in 1984, China's Patent Law has undergone three amendments: in 1991, 2000, and 2008. None of the amendments, however, defines the meaning of "on sale." Nevertheless, the traditional view is that China's Contract Law governs the interpretation of "on sale," partly due to the fact that "on sale" is considered to be a contractual behavior. Under China's Contract Law, "[a] sales contract is a contract whereby the seller transfers the ownership of a subject matter to the buyer, and the buyer pays the price for it."¹⁵ Two elements are essential in a sales contract, namely, transfer of ownership and payment. Since a sales contract can be performed either promptly or in the future,¹⁶ a patented product is "on sale" where a buyer expresses the intention to transfer the ownership of a subject matter and a seller, in return, expresses the intention to pay for the price. Under this interpretation, the time of the transfer of ownership and payment is irrelevant. Additionally, the sale of a product using the patented product as the component also makes the patented product "on sale."¹⁷

"Offer for sale," on the other hand, was added in the 2000 amendment,¹⁸ and it incorporates "offer" and "invitation for offer" into contract law.¹⁹ Specifically, it refers to "such behaviors as display in a store or an exhibition in trade show, being listed in a sales order or on an auction list, being listed in a promotional advertisement, or, through oral, written, or other means, expressly declaring an intention to sell certain products to specific or non-specific persons."²⁰ Thus, a patented product is held to be offered for sale as long as any of the enumerated behaviors or equivalent thereof has been manifested. The question then arises: Does every "sale" or "offer for sale" of the patented product render the invention prior art? And more importantly, what standard is applied when determining prior art under China's Patent Law?

"On-Sale Bar" Standard in China: Available to the Public

According to China's Patent Law, prior art refers to the technology that is *available to the public* before the effective filing date of the claimed invention.²¹ Unlike 35 U.S.C. § 102(a), under which the term "on sale" is disjunctively listed, such term is not separately listed anywhere in China's Patent Law. Hence, "available to the public" becomes the sole standard for determining whether an invention constitutes prior art.

Then what is "available to the public" under China's Patent Law? When deciding whether an invented technology is "available to the public," at least three factors are considered: (1) "what" exactly does the public disclosure encompass; (2) what

constitutes “public”; and (3) what constitutes “available”?

As for disclosure, China’s Guidelines for Patent Examination state that to constitute prior art, “substantive technical knowledge” of the invented technology must be available to the public.²² Therefore, merely touching upon the technical characteristics or general introduction, without more, such as disclosing substantive technical details, is not considered as prior art disclosure under the Guidelines.

As for making available to the “public,” an earlier case relating to a stereoscopic compass²³ at China’s Patent Re-Examination Board (PREB),²⁴ the Chinese counterpart of the U.S. Patent Trial and Appeal Board, sheds some light on how to interpret the phrase. In that case, the patent owner commissioned a manufacturer to build the prototype stereoscopic compass. The scope of the work is covered by a joint promotional agreement entered between the patent owner and the manufacturer. The manufacturer tried, but failed, to claim itself as a coinventor, largely due to its involvement in the production process. Not deterred, the manufacturer subsequently filed a petition to invalidate the patent because, as it rightfully claimed, the utility at issue had been available to the manufacturer and other persons and hence the whole invention had been made “available to the public.” The PREB disagreed. Specifically, the PREB stated that the owner and the manufacturer had a “particular partnership” which rendered the manufacturer a specific person, contrary to a nonspecific person²⁵ in the public. The PREB concluded that “the public” refers to “nonspecific persons.” In other words, if an invention is disclosed to multiple persons who are expressly or impliedly obliged to keep the invention confidential, it is only considered as available to multiple “specific persons”²⁶ rather than “available to the public.” And if a product is sold to only one person who has no obligation to keep the invented technical details confidential, this person constitutes a nonspecific person and hence the invention is “available to the public.” Similarly, the Guidelines further regulate that if the technical content is disclosed in either an express or an implied confidential relationship, then it remains secret and does not constitute prior art. However, and not surprisingly, the technical content becomes prior art if the obligor publicized the technical content in breach of confidential duty and made it available to the public.²⁷

Lastly, as for availability, the general rule is that if, after disclosure, any nonspecific person in the public can obtain the technical details as long as he or she is willing to do so, then the disclosure becomes “available” to the public. The availability inquiry is further complicated by the fact that there are three types of patents that can be issued in China: design, invention, and utility model.²⁸ Design patents protect the ornamental design of configuration, i.e., how a product looks.²⁹ And upon disclosure and regardless of the manifestation, an ornamental design becomes “available” to the public since it is seen by the public anyway. Both invention patents³⁰ and utility model patents³¹ are comprised of technical solutions and thus are not as apparent as ornamental designs. Therefore, a display of a product without giving away any technical specifications so that people of ordinary skill in the art can determine its structure, function, and/or material composition³² does not satisfy the “availability” inquiry. Practitioners in China also need to note that even if the structure or function of a product or device can be obtained only through deconstructing the product or device (e.g., reverse engineering), the invention is now considered as made “available.”³³

In addition to the aforementioned factors, the Guidelines further illustrate three ways for a technology to become “available to the public,” namely, description in a *printed publication*, *public use*, or *otherwise available to the public*.³⁴ Here, “otherwise available to the public” modifies “description in a printed publication” and “public use,” and thus serves as a catchall phrase. The Guidelines further define “public use” to encompass “manufacturing, use, *on sale*, import, exchange, gifting, demonstration, exhibition and other ways”; as long as the invented technical details are publicly available through those ways, the invention is publicly used regardless of whether it is actually known by the public.³⁵ It is worth mentioning that, similar to China’s Patent Law, “on sale” is not disjunctively listed under the Guidelines, but instead is encapsulated in the concept of “public use,” which in turn adopts the standard of “available to the public.” Therefore, for a “sale” behavior to defeat

the validity of a patent, the sale or offer for sale of the product must make the invention “available to the public.” Thus, under the standard of “available to the public,” for “on sale” to defeat a patent, all three of the following requirements must be met: (1) the invented technical details (or ornamental design) must be (2) available to (3) the public. A disclosure is not prior art if any requirement is not met. A sale of an invention to a third party that is statutorily, contractually, or impliedly obliged to keep the invention confidential does not qualify as prior art because this third party does not constitute “the public.” Put simply, a secret sale does not constitute an on-sale bar. Furthermore, neither an offer for sale nor a public sale qualifies as prior art if the general public cannot know the technical details by the offer for sale or public sale itself because these technical details are not “available.”

The courts have interpreted “available to the public” through sale similarly. Courts agree that for a sale or offer for sale of the patented product to invalidate the patent, the “technical details” of the invention must be “available” to the “public.” For example, in May 2008, a Supreme People’s Court case addressed all three inquiries of “available to the public.”³⁶ In *Rugao Aijike Textile Machinery Co.*, the technical details of the invention in question were recorded as an enterprise standard that had been put on records in the Quality and Technology Monitoring Bureau³⁷ pursuant to quality control regulation. Furthermore, the standardization regulation mandated that whenever a product is sold, the relevant code, number, and name of the standard the product executes must be marked on the product, product instructions, or packaging.³⁸ The Court concluded that the code, number, and name of the standard did not render the technical details of the invention available to the public because no evidence showed that the trading partners knew the technical details by simply referring to the code, number, and name of the standard. And even if the trading partners knew the technical details, they were obliged to keep the details secret. A takeaway from the Court’s opinion is that the code, number, and name of the standard the product executes, without more, do not make the technical details available.

Thus, in China, it is not as necessary to file a patent application before any secret sale activities since these activities may not render the invention available to the public. However, as mentioned above, if a person who owes a duty of confidentiality discloses the invention in some way, even if to only one nonspecific person, the invention will be regarded as being made “available to the public.” There is a partial cure to this problem, as “[a]n invention for which a patent is applied for does not lose its novelty where, *within six months* before the date of application . . . it was disclosed by any person without the consent of the applicant.”³⁹ Nevertheless, inventors still run the risk of losing their patent given the prevailing complexities in the Chinese market. And the solution to this issue is simply to file the application at an earlier stage, for the invention will not be published until 18 months after the filing date, and the patent office is entitled to wait for up to three years to examine the application.⁴⁰

Takeaways

An independent on-sale bar is nonexistent in China. Rather, an on-sale bar is included in the context of public use, which is one of the three ways to make the invention “available to the public”—the ultimate standard for prior art. Under this standard, neither a secret sale nor a public sale nor an offer for sale invalidates a patent so long as the public does not gain access to the technical details of the patent. Also, the good news is that, even after the invention (invention, utility model, or design patent) is disclosed to the public by any person without the consent of the applicant, the patent can still be issued so long as the disclosure is made within six months before the filing date. Accordingly, in case the invention is disclosed by any person to the public without an applicant’s consent, application for the patent must be filed as quickly as possible, but no later than six months after that unauthorized disclosure.

Now, after *Helsinn*, a secret sale of an invention will invalidate a U.S. patent no matter whether it happens in the United States, China, or other countries because the AIA removed the geographic limitation of the prior art disclosure. However, it will not invalidate a Chinese patent because secret sale per se does not make the invention available to the public. Therefore,

companies planning to obtain U.S. patents seem not to have much choice but to file as early as possible. And this early disclosure by filing in the United States alone will not bar the U.S. companies from obtaining a Chinese patent so long as it is within the grace period. To be specific, if a Chinese filing happens within 12 months (invention and utility model) or six months (design patent) after the same invention is first filed in the United States, the filing date of the U.S. application can be treated as the effective filing date of China's application.⁴¹

Endnotes

1. 139 S. Ct. 628 (2019).

2. 35 U.S.C. § 102(a)(1).

3. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67–68 (1998); *see also* *Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249, 257 (1887) (noting that “[a] single sale to another . . . would certainly have defeated his right to a patent”); *Consol. Fruit-Jar Co. v. Wright*, 94 U.S. 92, 94 (1877) (observing that “a single instance of sale or of use by the patentee may, under the circumstances, be fatal to the patent”).

4. 35 U.S.C. § 102(b)(1).

5. *Helsinn*, 139 S. Ct. 628.

6. Roche first launched phase I clinical trials but deemed the formulation unfavorable after the phase II study result and sold the formula to Helsinn, which completed the phase III trials and brought the drug to market after the FDA's approval. *See* Principal Brief of Plaintiffs-Appellees Helsinn Healthcare S.A. & Roche Palo Alto LLC, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017), 2016 WL 1698099, at *3–5.

7. *Helsinn Healthcare S.A. v. Dr. Reddy's Labs. Ltd.*, No. 11-3962, 2016 WL 832089, at *51 (D.N.J. Mar. 3, 2016).

8. *Helsinn*, 855 F.3d at 1371.

9. *Id.* at 1370.

10. *Helsinn*, 139 S. Ct. at 633.

11. *Id.* at 629, 634.

12. *Id.* at 633 (emphasis added).

13. Henry Grabowski et al, *Recent Trends in Brand-Name and Generic Drug Competition*, J. MED. ECON., 2013, at 1, <http://fds.duke.edu/db/attachment/2575>.

14. *See* DAVID THOMAS & CHAD WESSEL, BIO INDUS. ANALYSIS, EMERGING THERAPEUTIC COMPANY INVESTMENT AND DEAL TRENDS 32 (2018), <http://go.bio.org/rs/490-EHZ-999/images/BIO%20Emerging%20Therapeutics%20Company%20Investment%20and%20Deal%20Trends%20Report%202008-2017.pdf>.

15. Zhonghua Renmin Gongheguo Hetongfa (中华人民共和国合同法) [Contract Law of the People's Republic of China] (promulgated by the Nat'l People's Cong., Mar. 15, 1999, effective Oct. 1, 1999), art. 130, CLLI.21651(EN) (Chinalawinfo).
16. Zhonghua Renmin Gongheguo Hetongfa Shiyi (中华人民共和国合同法释义) [Interpretation of Contract Law of the People's Republic of China] (interpreted by the Legislative Affairs Comm'n of the Standing Comm. Nat'l People's Cong., Nov. 25, 2000), art. 130, cmt. 3(4), <http://www.npc.gov.cn/npc/c2196/200011/a03524fc967748af96e20a8e0f00bc52.shtml>.
17. Zhuanli Qinquan Xingwei Rending Zhinan Shixing (专利侵权行为认定指南(试行)) [Guidelines on Determining Behavior of Patent Infringement: Trial Implementation] (promulgated by the State Intellectual Prop. Office of the People's Republic of China, May 5, 2016), § 3, <http://www.sipo.gov.cn/docs/pub/old/wqyz/zctz/201708/P020170803330964698516.pdf>.
18. Zhuanli Fa (专利法) [Patent Law (2000)] (amended by the Standing Comm. Nat'l People's Cong., Aug. 25, 2000, effective July 1, 2001), art. 11, cl. 1, CLLI.31016(EN) (Chinalawinfo).
19. Guidelines on Determining Behavior of Patent Infringement: Trial Implementation, *supra* note 17, § 4.
20. Zhonghua Renmin Gongheguo Zhuanlifa Shiyi (中华人民共和国专利法释义) [Interpretation of Patent Law of the People's Republic of China] (interpreted by the Legislative Affairs Comm'n of the Standing Comm. Nat'l People's Cong., Aug. 1, 2001), art. 11 cmt. 1(1), <http://www.npc.gov.cn/npc/c2199/200108/57a15800fe1e4f6c81b94d15aadd0ad4.shtml>.
21. Patent Law (2000), *supra* note 18, art. 22, cl. 5.
22. Zhuanli Shencha Zhinan (专利审查指南) [Guidelines for Patent Examination] (promulgated by the State Intellectual Prop. Office of the People's Republic of China, May 24, 2006, effective July 1, 2006; revised Jan. 21, 2010, effective Feb. 1, 2010), pt. II, ch. 3, § 2.1, <http://www.sipo.gov.cn/docs/20191018163512108738.pdf>. Although the Guidelines, like the USPTO's *Manual of Patent Examining Procedure*, only govern patent examination, courts often cite the Guidelines to help determine prior art. *See, e.g.*, Xu Shichang Yu Zhonghua Renmin Gongheguo Guojia Zhishichanquanju Zhuanli Fushen Weiyuanhui (许世昌与中华人民共和国国家知识产权局专利复审委员会) [Xu Shichang v. State Intellectual Prop. Office, Patent Re-Examination Comm.], CLIC.1793600 (Chinalawinfo) (Sup. People's Ct. Jan. 24, 2013); Jiyin Jishu Gufen Youxiangongsi Yu Zhonghua Renmin Gongheguo Guojia Zhishichanquanju Zhuanli Fushen Weiyuanhui (基因技术股份有限公司与国家知识产权局专利复审委员会) [Genetic Tech. Co., Ltd. v. State Intellectual Prop. Office, Patent Re-Examination Comm.], CLIC.9653970 (Chinalawinfo) (Sup. People's Ct. June 29, 2016).
23. Guojia Zhishichanquaju Zhuanli Fushen Weiyuanhui (国家知识产权局专利复审委员会), Zhuanli Fushen Weiyuanhui Anli Quanshi: Xianyou Jishu Yu Xinyinxing (专利复审委员会案例诠释——现有技术新颖性), at 9 (2004); Zhuanli Fushen Weiyuanhui Wuxiao Xuanggao Qingqiu Shencha Jueding (Di Er Hao) (专利复审委员会无效宣告请求审查决定(第2号)) [Decision on the Patent Validity by Patent Re-Examination Bd. (No. 2)] (Patent Re-Examination Bd., Jan. 20, 1988), http://reexam-app.cnipa.gov.cn/reexam_out1110/searchdoc/decidedetail.jsp?jdh=WX2&lx=wx.
24. On February 14, 2019, the PREB ceased to exist, and all the works of the former PREB are now done by the State Intellectual Property Office.
25. A nonspecific person, as opposed to a specific person, has nothing to do with the concept of person of ordinary skill in the art (POSIA). It can include POSIA but not necessarily so. However, as will be discussed in the following “availability” inquiry, POSIA might be introduced to determine whether the invention is “available.”

26. The PREB does not specify the number of specific persons there needs to be.

27. Guidelines for Patent Examination, *supra* note 22, pt. II, ch. 3, § 2.1.

28. Patent Law (2000), *supra* note 18, art. 2, cl. 1.

29. *Id.* art. 2, cl. 4.

30. Invention patent refers to “any new technical solution relating to a product, a process or an improvement thereof.” Zhuanli Fa (专利法) [Patent Law (2008)] (amended by the Standing Comm. Nat’l People’s Cong., Dec. 27, 2008, effective Oct. 1, 2010), art. 2, cl. 2, CLI1.111782(EN) (Chinalawinfo).

31. Utility model patent refers to “new technical solution relating to a product’s shape, structure, or a combination thereof, which is fit for practical use.” *Id.* art. 2, cl. 3.

32. Guidelines for Patent Examination, *supra* note 22, pt. II, ch. 3, § 2.1.2.2.

33. *Id.*

34. *Id.* § 2.1. These three ways also appear in China’s Patent Law of 1984 as well as amendments in 1992 and 2000.

35. *Id.* § 2.1.2.2.

36. Rugaoshi Aijike Fangzhi Jixie Youxiangongsi Su Guojia Zhishichanquanju Zhuanli Fushen Weiyuanhui (如皋市爱吉科纺织机械有限公司诉国家知识产权局专利复审委员会) [Rugao Aijike Textile Mach. Co., Ltd. v. State Intellectual Prop. Office, Patent Re-Examination Comm.], CLIC.127337 (Chinalawinfo) (Sup. People’s Ct. May 20, 2008).

37. China’s governmental authority that is responsible for monitoring the quality of products made by business entities.

38. Zhonghua Renmin Hongheguo Biaozhunhuafa Shishitiaoli (中华人民共和国标准化法实施条例) [Regulations for the Implementation of the Standardization Law of the People’s Republic of China] (promulgated by State Council, Apr. 6, 1990, effective Apr. 6, 1990), art. 24, CLL2.4659(EN) (Chinalawinfo).

39. Patent Law (2000), *supra* note 18, art. 24 (emphasis added).

40. *Id.* art. 34 & art. 35, cl. 1.

41. *Id.* art. 29, cl. 1.

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