Comparison of Bolar Exception in China and the United States

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Constant efforts have been made in China and the United States of America in the protection of pharmaceutical or drug patents in an effort to strike a better balance between the interest of patentees and that of the public at large. Through nearly 200 years of development, the relevant issues have been explicated in great detail in the US case law and statute law. In China, law provisions along the line have also been developed and amplified. This article will be presenting an overview of some typical cases of and provisions on the exception to patent infringement, based on experimental use exception, Bolar exception, and non-infringement due to non-commercial purpose, in relation to clinical trials of new drugs in both countries. Furthermore, a comparison will be made to help readers know about the present situation and the expected future of the exception.

I. An overview of the US practice

The experimental use exception first appeared in the case law in 1813 in which acts of using patent only for scientific experimentation was held to be exempted from patent infringement. As time goes by, the coverage of the experimental use exception has been gradually narrowed. The Roche case in 1984 is widely viewed as a watershed between the experimental use exception and the Bolar exception. After Roche, the experimental use exception in the case law began to decline. The Madey case in 2002 was an official declaration of the end of experimental use exception in the case law. On the other hand, during over the 20 years after the Congress codified the Bolar exception provision in 1984, the courts have developed a broader and broader coverage of the Bolar exception, which gradually replaced the experimental use exception and became a safe harbor for exempting clinical trial of drugs from patent infringement.

1. Gradual decline of experimental use exception in the case law

1) Application of experimental use exception

In the Whittemore case[1] in 1813, where the experimental use exception was first applied, the US Supreme Court stated that the law was not meant to punish those undertaking scientific experimentation. In applying the experimental use exception in the Sawin case[2] in the same year, the Supreme Court held that an accused infringer's intent was a key factor in determining infringement liability. In the following over 150 years, the experimental use exception was repeatedly cited in court. Until the second half of the 20th century, especially after the Roche case, the courts have been gradually narrowing the coverage of the experimental use exception.

2) The Roche case[3]: the experimental use exception should not apply to acts with business purposes

In the Roche case in 1984, the Roche Corporation (the plaintiff) owned a patent for the effective ingredient of the sleeping pill. The Bolar Corporation (the defendant) was a generic drug manufacturer, devoted to making succedaneum of patented ones. To grab market share, a generic drug manufacturer usually hopes to put a drug into the market immediately after the term of the patent expires, as the drug which enters the market first often takes up the largest market share. However, to launch a drug in the market, one has to obtain approval from the Food and Drug Administration (FDA) first. Under the FDA's regulations, it would take more than two years to obtain the regulatory approval, even through the Abbreviated New Drug Application (ANDA). In other words, the defendant, anxious to market a drug right after the expiry of the patent, had to file an application with the FDA before the expiry of the patent, containing data necessary for the FDA's regulatory approval.

In this case, the defendant acquired some patented drugs from abroad six months before the patent expired, and gained the necessary data from the experimentation of said drug. The district court found that the accused act was for the purpose of research and experimentation, and ruled

in favor of the defendant.

The Court of Appeals for the Federal Circuit (CAFC) reversed the district court's ruling, holding that the application of experimental use exception should not have been expanded to those applications "for business purposes". In other words, the experimental use exception should not apply to an act for business purposes, be it an experiment or not. In the present case, in the last six months of the term of patent protection, the accused study was closely related to the FDA's drug approval, which was an act purely for business purposes; hence, the experimental use exception should not apply. The CAFC ruled in favor of the plaintiff.

In the present case, the CAFC held that the experimental use exception to patent infringement should not apply to acts for business purposes. However, what extent of business purpose would preclude experimental use exception from applying to acts of experimentation? This question was answered in the Embrex decision in 2000.

3) The Embrex case[4]: The experimental use exception should not apply to acts even they are slightly related to business purposes

In the Embrex case in 2000, the CAFC again refused to apply the experimental use exception to patent infringement as, besides the purpose of scientific exploration, the defendant used the patented medical device in experiments for the purpose of demonstrating its product to potential customers. In his concurring opinion in the judgment, Honorable Judge Rader said that the experimental use exception should not apply to acts even they are slightly related to business purposes.

After that, the ruling made in the Madey case in 2002 is believed to be the last nail to the coffin of experimental use exception.

4) The Madey case[5]: The experimental use exception should not apply as long as the accused act was done in furtherance of commercial use.

In the Madey case, the CAFC held that the Duke University's use of the patented laser device in academic research fell outside the experimental use exception. Further, the CAFC held that whether the accused party acted for business purposes or not, the experimental use exception should not apply as long as the act was done in furtherance of use in a certain aspect, even indirectly, say improving the appearance of the campus or attracting fund, students, and faculty.

This shows that by the year of 2002, the experimental use exception has been so narrowly limited in the US case law that even such non-profit institutions as universities would find it hard to use the experimental use exception. Besides, even if an act per se was not for business purposes, the experimental use exception should not apply if such an act was done in furtherance of use.

By then, the experimental use exception was eventually put to an end in the case law, and was replaced by the Bolar exception codified in 1984.

2. Emerging and development of the Bolar exception

1) Hatch-Waxman Act

In the above-mentioned Roche case in 1984, the defendant Bolar argued that if the experimental use exception should not apply, a generic drug manufacturer was unable to make clinical trial for gaining the data required for the FDA approval until the expiry of the relevant patent. As a result, it was quite possible that the drug could only enter the market years after the expiry of the patent, which virtually meant an extension of the protection for the patentee, prejudicing the public's interest. Hence the defendant argued that the act of clinical trial should not be ruled as an infringement.

The CAFC did not support the argument because it involved the issue of how to maximize public interest, and CAFC was not the proper venue to review public policy. It was the Congress's responsibility to balance the interests between the public and the patentees; hence the Congress should address the issue legislatively. Under the law provisions then in force, the court had to hold in favor of plaintiff.

The judgment made in the Roche case caused much uproar in the industry, and many major generic drug manufacturers lobbied to the Congress. In response, the Congress issued in the same year the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act.

The Hatch-Waxman Act mainly addressed two issues. First, to address the issue of impossibility to put a drug on the market right after the expiry of a patent that results in the extension of the term of said patent. To that end, §202 allows a generic drug manufacturer to make clinical trial and gain the data necessary for the FDA's regulatory approval before a patent expires. Second, given that a patentee's inability to market a patented product right after grant of the patent due to FDA's regulatory approval means a loss of part of the term of said patent, the Hatch-Waxman Act provides that the term of a patent in respect of which the FDA's regulatory approval takes too long may be extended. Later, §202 was codified in

the § 271 (e) (1) of the 35 U.S.C., namely the Bolar exception provision[6].

In the following almost three decades, the courts gradually expanded the coverage of the Bolar exception. In 1990, the "patented product" was interpreted as including medical devices in the Medtronic case. Later in the Intermedics case in 1991, "reasonably related" was interpreted in a way beyond the original intention of the law provision. In the Merck case in 2006, the scope of the Bolar exception was expanded to cover the clinical trials for gaining information that's not eventually submitted to the FDA. Most recently, the court in the Amgen case in 2007 ruled that making a drug with a patented process also fell within the coverage of the Bolar exception. Step by step, the Bolar exception has gradually taken the place of the experimental use exception in the case law.

2) The Medtronic case[7]: the Bolar exception also applies to medical device

Literally, the Bolar exception provision of the US Patent Act covers only drugs or pharmaceuticals, without mentioning medical devices. But, in the Medtronic case in 1990, the Justice Scalia held that the "federal law", as referred to in the Bolar exception provision, covered medical device and food additives in addition to regulation of drugs or pharmaceuticals. The reason for the provision not to expressly cover medical devices, is lack of careful drafting. For that matter, Justice Scalia decided that "patented invention" included medical devices. Further, besides the medical devices of the third class under the Food, Drug and Cosmetic Act (FDCA), the CAFC decided, in the Abtox case[8] seven years later, that the medical devices of the second class were also the "patented invention" as defined in the Bolar exception provision. Further, in the Amgen case to be discussed in the following section, the CAFC included products made with patented processes or methods in the coverage of the "patented invention".

3) The Elan case[9]: Two possible interpretations of the Bolar exception

In the Elan case, the court found, for the first time, that the Bolar exception provision would give rise to ambiguity. The provision prescribes that "it shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention ... solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." In English, this provision may be interpreted in two ways: one, it is not an infringement to make, use, offer to sell, or sell a patented invention as long as it is reasonably related to the development and submission of information to the FDA for regulatory approval, even the act is also related to other purposes, such as business purposes; and two, it is not an infringement to make, use, offer to sell, or sell a patented invention for uses solely reasonably related to the development and submission of information to the FDA for regulatory approval. In other words, said acts must be merely related to gaining of data for the FDA's regulatory approval, not for any other purposes. In practice, clinical trials in purpose of drug development often involve preparatory work before a drug is put on the market, that is, for gaining of the FDA data, and possibly for other uses. Then, is this an act falling within the Bolar exception? A relatively clear answer was given in the Intermedics case in the following year.

4) The Intermedics case[10]: The Bolar exception applies to acts for business purposes as long as they are related to gaining data for the FDA's regulatory approval

In this case, the plaintiff owned a patent for implantable defibrillator. The defendant, to grab the market after the patent expired, made clinical trial of said implantable defibrillator, and gained data necessary for filing the pre-market application (PMA). During the clinical trial, the defendant made hundreds of implantable defibrillators; sold them to hospitals in the U. S.; sold them to foreign retailers; and tested them outside the US.

The CAFC's considerations mainly focused on the two points as follows:

i) whether the defendant's act fell within the coverage of "reasonably related";

ii) what if it went beyond the coverage of "reasonably related".

The court made the ruling regarding defendant's four acts:

(1) the manufacture of the device was infringing but the device was used to obtain FDA approval;

(2) the sale of the devices to United States hospitals were for collecting clinical data and that no sales of the devices occurred to non-clinical participants. Even though sales continued after the PMA was filed, this was defensible since the applicant can't know whether the PMA data was sufficient or whether further clinical data would be needed;

(3) the sales to international distributors who subsequently resold the devices to authorized, but foreign, clinical

doctors whose responsibilities included collecting information was allowed; and

(4) the test in Germany was to collect data and that submission to the FDA of data derived from foreign testing sites was allowed, especially since the German doctors were pre-eminent doctors in the field of cardiology.

In this case, the CAFC explained that "the court refused to equate the word 'uses' with the word 'purposes' and said that Congress intended the test to be one of conduct, or actual uses, rather than motive."

In this case, the CAFC broadly interpreted "reasonably related", which is in accordance with the first interpretation put forth in the Elan case, viz so long as to the use of a patented product is reasonably related to gaining data necessary for the FDA's regulatory approval, the Bolar exception applies to the act, even if it is related to business purposes. This interpretation has expanded the practical coverage of the Bolar exception beyond the coverage intended by the original law provision. Later, in the Integra case in 2005, the US Supreme Court made an even broader interpretation of the Bolar exception.

5) The Integra case[11]: It is also possible for the Bolar exception to apply to preclinical studies even if information gained there from is not eventually submitted to the FDA.

The Merck (the defendant) entrusted Scripps Corporation with experimentation with animals to identify potential pharmaceutical candidates likely to inhibit generation of blood veins. In the research, Scripps Corporation first identified three potential polypeptides, then made experiments to evaluate the particularities, effect and toxicity of these polypeptides. However, not all the data from the experiment were eventually submitted to the FDA. Integra (the plaintiff), owner of the patent relating to these polypeptides, sued Merck for infringement.

From the very beginning, the discussion was focused on three issues involved in the case:

i) The patented drugs were used in the pre-clinical studies, but the information gained was not eventually submitted to the FDA. In case like this, was such act still "reasonably related"?

ii) Unlike the previous cases, the defendant in the present case did not use the patented products for making substitution pharmaceuticals. Rather, it used them as research tools to develop new drugs. Then, should the Bolar exception apply to such an act?

iii) The defendant did not experimented on human body, but on animal. Did the Bolar exception apply to acts of experiment on animal?

Both the district court and the CAFC found infringement, holding that the Bolar exception applied to acts of experiment only if the resulting information is eventually submitted to the FDA.

However, the Supreme Court reversed the ruling and delivered a unanimous opinion: (1) the exemption set forth by § 271 (e)(1) includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process; (2) the exemption is not limited only to preclinical data pertaining to safety of drugs in humans; and (3) the exemption does not categorically exclude either experimentation on drugs that are not ultimately the subject of an FDA submission or the use of patented compounds in experiments that are not ultimately submitted to the FDA.

In addition, the Court explicitly stated in a footnote that it was not expressing an opinion as to whether § 271 (e)(1) exempts "research tools" from infringement in the development of information for the regulatory process. However, some amicus briefs filed with the Court suggested that a patented research tool did not fall within the coverage of § 271 (e)(1) because a research tool was not the actual or potential subject matter of the application submitted for review to the regulatory authority.[12]

The case was then remanded to the CAFC, and the CAFC made another judgment of non-infringement on 27 July 2007. Judge Newman decided mainly as to the following two aspects:

(1) challenged experiments met criteria of being reasonably related to research that, if successful, would have been appropriate to include in submission to Food and Drug Administration (FDA)s, and

(2) challenged experiments were not deprived of FDA exemption to patent infringement by their contribution to scientific knowledge.

Unfortunately, on remand, the CAFC did not address the issue of research tool used in the retrial. In the retrial, the two parties and the CAFC denied that the patented products had been used as research tools. The issue was not touched upon, and was yet to be dealt with in future cases.

6) The Amgen case[13]: The Bolar exception also applied to products made with patented process if the "reasonably related" requirement was met.

In the latest Amgen case, Amgen (the plaintiff) filed a complaint before the International Trade Commission (ITC)

alleging Roche (the defendant) infringes six of its patents by importing into the United States recombinant human erythropoietin and its derivatives (collectively known as EPO). The defendant argued that since the imported drug was used to gain data for the regulatory approval from the FDA, the act of import should not be deemed to be an infringement as the Bolar exception might apply. The ITC supported its argument, and decided that its act was not an infringement.

In its appeal to the CAFC, the plaintiff argued against applying the Bolar exception on the ground that the goods being imported was not "patented product". Rather, the defendant used the plaintiff's patented process to make the drug which was then imported into the United States.

On 14 October 2007, the CAFC affirmed, holding that the Bolar exception provision applied to acts of importing drugs made with patented processes. In the ruling, the CAFC cited Integra and Medtronic cases. The court reiterated that the Bolar exception applied as long as an act of using a patented invention was reasonably related to gaining data necessary for the FDA's regulatory approval. In the Medtronic case, the court pointed out that the "patented inventions" mentioned in the Bolar exception was not restricted to pharmaceutical inventions. Now that the defendant's act was reasonably related to gaining data necessary for the FDA's regulatory approval, and the "patented inventions" mentioned in the Bolar exception provision was not strictly confined to pharmaceutical inventions, why shouldn't the Bolar exception apply to the defendant's act? Accordingly, the CAFC upheld the ITC's decision, holding that the Bolar exception should apply to the defendant's act of importing the drug made with the patented process, and such acts were not deemed to be an infringement.

II. An overview of Chinese practice

The Chinese Patent Law was enacted in 1984. According to the general provisions, the use of a patent without authorization for the purpose of experimentation and research was exempted from patent infringement. In the first dispute involving clinical trial, the court ruled in favor of the patentee. How to define the boundary between the experimental use exception has long been troubling the authorities. Scholars have come up with explanations, and the Beijing Higher Court has also developed its relevant judicial recommendations. In 2002, the State Food and Drug Administration put in place a limited "patent linkage" system, providing a way to deal with conflicts between regulatory approval of new drugs and patent infringement. Meanwhile, these conflicts drew attention from the courts and the State Intellectual Property Office (SIPO). The Beijing Higher Court and the Supreme Court respectively put forth, one after another, opinions and drafted proposals on the experimental use exception, while the SIPO proposed to add a Bolar exception to the Patent Law. Between 2006 and 2007, the courts in Beijing handled a series of cases of patent infringement arising from clinical trials, and decided that clinical trial of patented drugs for regulatory approval did not constitute patent infringement due to its non-commercial purpose.

1. Definition of patent infringement and experimental use exception in the Patent Law

The Patent Law, as first enacted in 1984 in China, generally provided for the circumstances of patent infringement as follows:

"After a patent for invention or utility model is granted, unless otherwise provided for in the law, no entity or individual shall exploit the patent without authorization, that is, it or he shall not make, use or sell its or his patented product, or use its or his patented process for business purposes."

And the experimental use exception as follows:

"Anyone of the following circumstances shall not be deemed to have constituted patent infringement: … (4) using a patent solely for scientific research and experimentation."

The Patent Law was amended twice in 1992 and 2000 respectively, and the preceding provisions remain substantially unchanged, only renumbered [14].

2. Glaxo v. Southwest, where the court implicitly affirmed that clinical trial of new drug constituted patent infringement

Ten years after the Chinese Patent Law entered into force, the first dispute arising from patent infringement involving clinical trial was handled by the court in 1995.

In this case, the plaintiff Glaxo owned invention patent ZL85105643, claiming a method for preparing the drug of Ondansetron and the relevant compounds. Upon learning that the Southwest Pharmaceuticals Plant had prepared Ondansetron and used it in its clinical trial of the new drug, and was granted the new drug certificate by the Ministry of Health, the plaintiff sued in May 1995 in the Chongqing Intermediate Court, seeking injunction, public apology, and damage of RMB 320,000 yuan, which was calculated by multiplying the quantities of the drugs (supplied to hospitals) made by the defendant during its clinical trial of the new drug with the unit profit of the plaintiff's drug.

In said case, refusing to furnish the proof of the method for making its products, the defendant failed to meet its statutory burden of proof. Therefore, the Court legally deemed that the accused method was identical with the plaintiff's patented method, and granted injunction and total damages claimed by the plaintiff.[15]

In the Glaxo's case, while not specifying whether the use of another party's patent during clinical trial of a new drug constituted an infringement or not, the court granted the total damages caused during the clinical trial of the new drug, which implied that the trial constituted infringement.

3. Academic understanding of experimental use exception and "production and business purposes"

The Glaxo ruling involves interpretation of the acts of patent infringement mentioned in Article 11 and the experimental use exception mentioned in Article 62 (5) of the Patent Law as of 1984.

The term experimental use was interpreted in the Interpretation of the Patent Law published before the Glaxo case:

"The expression of 'solely for scientific research and experimentation' means the research is conducted only for the purpose of scientific research and experimentation is performed only for the purpose of experimentation; the use of a patent includes the use of patented product in scientific research and experimentation, and includes performing scientific research and experimentation on products made by the patented process as well".[16]

The term experimental use was also interpreted in the Interpretation of the New Patent Law published after the Glaxo case:

"This Article provides for 'use of a patent for scientific research and experimentation', in which the expression 'scientific research and experimentation' refers to those made specifically of the patented technology, for the purpose of identifying the technical features or technical effect of the patented technology, or for the purpose of making further improvement of said patented technology; it does not refer to general scientific research and experimentation; said 'use of a patent' means making a patented product or using a patented process according to the published patent documents for said purpose, analyzing or reviewing the patented technology, rather than using the patented technology as a tool to conduct other scientific research and experimentation."

In the Interpretation of the New Patent Law, "for the production and business purposes" is interpreted as:

"The so-called 'for the production and business purposes', which covers a wide range, means for the purposes of industrial or agricultural production or business operation. 'For the production and business purposes' should not be construed as 'for the purpose of making profit', which covers a much narrower scope, and such a stringent limitation should not be imposed on the protection of the patent rights.

Whether a certain act is done for the production and business purposes may be determined from three perspectives: the mode of the act, the actor and the nature and scope of an act. As for the mode of an act, sell and offering for sale are generally considered to be for the production and business purposes, regardless of whether the actor is an entity or an individual; making, using and importing may sometimes be considered to be for the production and business purposes, but sometimes not. As for the actor, an act carried on by an enterprise or profit entity is usually for the production and business purposes, while an act done by a government agency, non-profit institution, or social organization is usually not for the production and business purposes. The nature and scope of an act should be specifically determined according to the practical circumstances under which the act has been performed. It should be specially noted that the nature of an entity is by no means the key factor in determining an act of exploiting a patent, and an act of making, using or importing by a government agency, non-profit institution, or social organization may possibly be conducted for the production and business purposes in nature. For example, a hospital uses a patented device for treatment of a disease."

In respect to "the production and business purposes" and "experimental use", it is stated in the Interpretation of the New Patent Law as follows:

"Today when the market economy system is being established in China, it is virtually meaningless to discuss whether the research and experimentation are for the scientific or commercial purposes, as the two are very much related. Besides, the gap between them is now being narrowed in China to make them more closely related to or associated with each other. Therefore, in determining whether this provision is applicable or not, attention should not be focused on the matter of whether an act is done for scientific or commercial purposes."[17]

4. The Beijing Higher Court's guiding opinions on experimental use exception

In 2001, the Beijing Higher Court developed the Opin-

ions on Several Issues Relating to Patent Infringement Adjudication (Tentative), and issued it to the Beijing Nos.1 and 2 Intermediate Courts for implementation. Article 98 thereof provides as follows:

"Any act of using the patent solely for the purpose of scientific research and experimentation is not deemed to be an infringement of the patent right. In this regard, a distinction should be made between the experimentation on the patented product and use of the patented product in experimentation.

1) The use of the patent solely for the purpose of scientific research and experimentation should include the act of manufacturing;

2) The use solely for the purpose of scientific research and experimentation is for the purpose of studying, testing or improving another person's patented technology and the result of this use is the making of a new technology achievement on the basis of the existing patented technology; and

3) The manufacture with, or use of, another person's patented technology in the course of scientific research and experimentation, which is not for the purpose of research or improvement of another person's patented technology, with the result being not directly related to the patented technology, constitutes an infringement of the patent right."

5. The State Drug Administration's establishment of the limited "patent-linkage" system

Usually, a patentee, when finding that a generic drug to be registered infringes her patent right, reports to the State Drug Administration, the new drug approval authority, seeking suspension or rejection of the application for the regulatory approval of said new drug. In the early practice, the State Drug Administration would state in written approval of a new drug that "the technology for making the present drug possibly conflicts with another party's patent. The applicant of the new drug shall be responsible in case of patent infringement dispute."

In 2002, the State Drug Administration promulgated the Measures for the Registration and Administration of Drugs. Article 11 thereof requires that "an applicant for the registration of a drug shall present all the Chinese patents related to the drug applied for registration or the prescription or process for making the drug, and explain the ownership of the patents, guarantee that the registration does not infringe any other party's patents, and promise that it or he would be responsible for the liabilities of any possible infringement"; Article 13 provides that "as for a drug for which a Chinese patent is granted, another party may file an application for registration of said drug within two years before expiry of said drug patent; the State Drug Administration shall examines the application under these Measures and approve the registration of the drug that meets the provisions for production or importation after the patent expires"; and Article 12 shows the approach to dispute resolution: "where a dispute arises from patent infringement after approval of the registration of a drug, the interested parties may resolve the dispute themselves, or by the judicial authority or an administrative agency under the relevant laws or regulations".

It is worth noting that Article 13 of the Measures for the Registration and Administration of Drugs as of 2002 disallows application for regulatory approval of a generic drug to be filed two years before the expiry of the patent.

6. The Supreme Court's draft of interpretations on the experimental use exception

The conflicts of clinical trial and regulatory approval of new drugs with patent infringement have drawn attention from the Supreme Court.

In 2003, the Supreme Court drafted the judicial interpretation, the Provisions on Several Issues Relating to Trial of Cases of Dispute From Patent Infringement, wherein Article 84 (2) provides as follows:

"Where a patented product is made or used, or a patented process is used, and a product directly obtained with a patented process is used in clinical trial in order to exploit a patented technology immediately after expiry of the patent, the Court shall deal with the matter under Article 63, paragraph one (4) of the Patent Law".

In other words, exploitation of another party's patented technology for the purpose of regulatory approval of a new drug is brought within the coverage of experimental use exception under the drafted interpretations. These drafted interpretations are yet to become effective despite rounds of discussion.

7. The State Council and the SIPO: Amendment to the Patent Law by addition of the specific provisions similar to the Bolar exception

In 2006, the SIPO proposed amending the Patent Law, and one of the proposed amendments was to be made by adding specific provisions similar to the Bolar exception to the Patent Law. According to the proposal in Article 74, the acts which are not deemed to be the infringement of patent right include:

…

"(6) the making, using or importing of a patented pharmaceutical product or patented medical device solely for obtaining and providing information necessary for the regulatory examination and approval of the pharmaceutical product or medical device, and the making and importing of the patented pharmaceutical product or patented medical device and sale of the product or device for the above-identified purpose."

Besides, the experimental use exception as provided for in Article 63, paragraph four of the present Patent Law is kept as paragraph five of Article 74:

"(5) using a patent solely for the purposes of scientific research and experimentation," (shall not be deemed to have constituted a patent infringement)

The SIPO has submitted the Draft Amendment to the Patent Law to the State Council for review. Like the Supreme Court's drafted Provisiions, these amendments are yet to become effective.

8. Sankyo v. Wansheng[18] where the court held that clinical trial of a new drug and application for regulatory approval of production thereof are not for the production and business purposes

In this case of patent infringement, the court has given its explicit judicial view on the matter of whether or not use of another party's patent during clinical trial constitutes a patent infringement.

The plaintiff, the Sankyo Corporation owned an invention patent (ZL 97126347.7), claiming a method for making the pharmaceutical compound olmesartan and the relevant compounds; the co-plaintiff, the Sankyo Drug Manufacturing Corporation, was the non-exclusive licensee of said patent. They learned that the defendant, Beijing Wangsheng Drug Industry Co., Ltd., was infringing the plaintiff's patent by having made a lot of pharmaceutical tablets of "Olmesartan medoxomil" in the course of applying for the registration of the new drug and for the regulatory approval of making the same.

Upon hearing the case, the Beijing No.2 Intermediate Court held that

"Although the defendant used the patented process in suit to make said drug for the purposes of clinical trial and for applying for the regulatory approval of the production, its act of making the drug was done to meet the requirement of the relevant State agency for the regulatory approval of the drug by testing the safety and effectiveness of the drug it made. Given that the defendant did not make the drug in suit directly for the purpose of marketing it, its act was not to exploit the patent for the production and business purposes as defined in the Patent Law of the People's Republic of China. Accordingly, it was decided that the defendant's act did not constitute an infringement of the patent right in suit."

In this case, the court did not interpret the experimental use exception provided for in Article 63 of the Patent Law, but explained the provision on "for the production and business purposes" in Article 11. In the ruling on said case, it seemed that the court tried to avoid any potential conflicts with the SIPO's draft of the Amendments to the Patent Law and with the proposals made by the Supreme Court with regard to the experimental use exception, but to creat another harbor for the new drug registration applicants from bearing patent infringement liability due to its use of another party's patent in clinical trial of the new drug. Since the parties of Sankyo case did not appeal, the ruling in the case has become effective.

9. Lilly v. Ganli[19] where the court reiterated that clinical trial of new drugs and application for regulatory approval of production thereof are not for the production and business purposes.

After the Sankyo case, the Eli Lilly and Company brought the same issue before the Beijing No.2 Intermediate People's Court. Since the patents in suit related to 5 independent patents, the court heard them in five separated cases.

Lilly complained that Ganli's acts to apply, with the State Food and Drug Administration, for the regulatory approval of the "recombinant insulin lispro" and "biphasic recombinant insulin lispro injection 75/25", and advertise on the internet the medicament "Prandilin" (having the insulin lispro as the active ingredient) infringe its patents.

The court held that, based on the evidence available, Ganli's accused infringing medicament "recombinant insulin lispro " and "biphasic recombinant insulin lispro injection 75/25" were pending in the stage of the regulatory examination for approval for registration, and were not ready to enter the market. While the defendant made the clinical trial and applied for the regulatory approval of production, it acted to meet the requirements imposed by the relevant State agency for regulatory approval of drugs and test the safety and effectiveness of the drug it had made. While the "recombinant insulin lispro injection" Ganli applied for was granted the regulatory approval and ready to enter the market, Lilly failed to present evidence to show that Ganli had accordingly

made and marketed said drug. Therefore, Ganli's act of making the drug in suit was not done directly for the marketing purposes, so it was not an act of exploiting another party's patent for the production and business purposes as defined by the Chinese Patent Law.

As for Ganli's advertisement of the drug "Prandilin" published on the internet, the court held that it should not be determined that Ganli had used the product directly obtained with Lilly's patented method. Besides, no available evidence shows that Ganli had actually made the drug for marketing. Accordingly, Lilly's claim that Ganli's acts constituted an infringement was not based on sufficient evidence and was not supported by the court.

Lilly appealed two of the five first-instance judgments to the Beijing Higher Court, and the Beijing Higher Court recently affirmed the trial court's rulings, which means that the rulings made by the Beijing No.2 Intermediate People's Court on Lilly cases now come into effect, and the judicial view as embodied therein has a far-reaching impact on the clinical trial of new drugs and regulatory approval of production thereof. Like in the Sankyo case, the court only explained the provision on "for the production and business purposes" as mentioned in Article 11 of the Patent Law, without citing the provision on experimental use exception of Article 63.

10. Possible future developments

The Sankyo case has changed the ambiguous view of the Glaxo court, and made it clear that use of another party's patent for the purpose of regulatory approval of a new drug does not constitute a patent infringement. Given that the rulings on the Sankyo case and Lilly cases have taken effect, the conclusion made in the cases now serves as a judicially valuable reference and it will be a judicial conclusion in China that an act of using another party's patent for the purpose of regulatory approval of a new drug is not one performed for production and business purposes, so not an infringement of a patent .

On the other hand, it may be reasonably anticipated that the more detailed provisions on the experimental use exception and on Bolar exception will be written into statute in the near future.

III. Comparison between China and the United States

In this section, first, the interpretations of "for the production and business purposes" and "for commercial purposes" will be compared between the two countries. Then, a comparison will be made as to the experimental use exception between China and the United States. Last, but by no means the least, the interpretations of Bolar exception will be compared in four aspects.

1. "For production and business purposes" or "commercial purposes"

Under the present situation where the Bolar exception is absent in the Chinese Patent Law, the Chinese courts' adjudicative basis for ruling the use of patent without authorization in clinical trial as non-infringing is that the use is not for "the production and business purposes", which created an umbrella of protection under the current framework of the Patent Law for generic drug manufacturers' use of others' patents for the purpose of new drug registration, as in Sankyo case and Lilly cases.

The US courts ruled in the Roche, Embrex and Madey cases that the experimental use exemption did not applied to the accused acts which were for business purposes, slightly for business purposes, in furtherance of commercial use, respectively. These conclusions are different from that drawn in the Sankyo case and Lilly cases in China.

In the Intermedics and Integra cases, the US courts also found the commercial purposes of the accused acts. But, based on the Bolar exception statute, the courts were very tolerant toward such purpose. Presence of the commercial (or production and business) purposes did not affect the application of the Bolar exception. Bolar exception applied to an accused act even if it was for commercial purposes, so long as it was related to gaining data for the FDA's regulatory approval. The non-infringement conclusion was the same as that drawn in the Sankyo case and Lilly cases in China, but with different reasoning.

2. Experimental use exception

In China, in the Glaxo case, while it was not explicated in the ruling whether the clinical trial constituted a patent infringement or not, the court granted total damages caused during the defendant's clinical trial of the new drug. This demonstrated the judge's intention of not applying the experimental use exception. And according to the Beijing Higher Court's guiding opinions (2001) it would be harder to exempt a new drug registration applicant from patent infringement liability under experimental use exception when the applicant uses a third party's patent without authorization. Although the Supreme Court drafted in 2003 a Provision that interpreted experimental use exception as provided for

in Article 63(4) of the Patent Law to cover the situation of using a third party's patent for the purpose of new drug registration and regulatory approval, the draft interpretation has not yet come into force. As a result, in the judicial practice, say, in the cases involving Sankyo and Lilly, the court did not accept clinical trial of a new drug as a circumstance of experimental use exception in the sense of the Patent Law.

In the proposed third amendment to the Chinese Patent Law, the former Article 63 (4) on the experimental use exception will be kept as Article 74 (5). According to the Interpretation of the New Patent Law and the Beijing Higher court's opinions, in China, scientific research and experimentation solely refer to those made in improving a patented technology per se, not to the use of a patented product or process to develop another product, and such use includes "making, using or importing a patented product, or using a patented process, and making, importing and marketing a patented product for the purpose of the use".

In the US, in the Roche case, the CAFC reversed the low court's decision, holding that the accused infringing act was for commercial purpose, to which the experimental use exception should not apply. In the later Embrex and Madey cases, the CAFC decided that the experimental use exception to patent infringement did not apply so long as the accused act was performed slightly for commercial purpose or in furtherance of commercial development.

Comparatively speaking, regarding the experimental use exception in the United States, it is impossible for it to apply to any act that is slightly related to commercial purpose, and even indirectly promotes commercial development. It may be said that the conditions for the application of experimental use exception is much more stringent in the United States.

3. The Bolar exception

3.1 medical devices

The Bolar exception provision of the U.S. Patent Act covers drugs or pharmaceutical, but mentions nothing about medical devices. Later, in the Medtronic case, the Supreme Court held that the Bolar exception also applied to the medical devices and explained that the reason why medical device was left out of the provision at the beginning was lack of careful drafting. Similarly, China directly proposed in the third amendment of Patent law that the Bolar exception was applicable to the medical devices. It is apparent that the two countries take more or less the same attitude in this regard.

3.2 "solely for"

In the United States, when Bolar exception was initially codified, the wording, particularly "solely for", appears to be limiting the application to the clinical trials that were solely reasonably related to obtaining the data required for FDA approval. However, in the Intermedics case and other cases later on, the courts extended the application of Bolar exception to those clinical trials that were not only reasonably related to obtaining the data required for FDA approval, but related to other purposes like commercial purposes.

Just like in the United States at the early stage, the Bolar exception in the proposed third amendment of Chinese Patent Law restrains its application to those clinical trials that are solely related with obtaining the data required for drug registration. In other words, Bolar exception would literally be non-applicable to the clinical trials that are also related to commercial goals and only applicable to those clinical trials which are not related with commercial goals. However, the clinical trials without commercial goals are by definition not infringing according to Article 11 of the Patent Law, as decided in the Sankyo case and Lilly cases. Why bother applying Bolar exception?

After watching the expansion of Bolar exception in the United States over the years, one can't help wondering whether the Bolar exception will also be broadened in China, so as to cover those clinical trials that are related to other purposes than the FDA-related purposes. If so, one possibility is that the Chinese legislative authority will amend the proposed Bolar exception provision to literally cover those clinical trials that are related to commercial purposes in addition to obtaining FDA data, for example, by deleting the limitation of "solely for" in the provision. Another possibility lies in that the Chinese courts give the provision a broad interpretation when it comes to infringement disputes, despite that the provision is literally limited to the FDA-related uses.

3.3 Drugs and medical devices made with patented processes

According to the Amgen decision, the Bolar exception applies to use of products made with patented processes if the use is related to the FDA data.

Relatively, the Bolar exception provided for in Article 74 (6) of the proposed Third Amendment to the Chinese Patent Law is literally directed to "patented pharmaceuticals or medical devices". It is impossible to reach similar conclusion in China to that in the United States.

Nonetheless, considering the inclusion of enforcement of the patent rights for processes in the Sankyo and Lilly cas-

es, if the use of a product made with a patented process is an exploitation of the process patent solely for obtaining and providing information necessary for the regulatory approval of a drug or medical device, then the "patented pharmaceuticals or medical devices" mentioned in said provision would possibly be construed as covering "drugs or medical devices made with process patents". In this regard, the two countries shall also take similar attitude.

3.4 Extended term of protection

As discussed above, it is provided in another provision of the Hatch-Waxman that to make up for the period of time a patentee loses in the beginning of the patent term due to the FDA's regulatory review, the term of a patent may be extended. The extended term is a compensation to the patentee's legal interests by offsetting the extra protection under the Bolar exception statute. In contrast, the proposed Chinese Bolar exception provision is silent about the extension of the patent term, in other words, the Chinese Bolar exception is in favor of the public when it comes to the balance between the interests of the public and the patentees.

IV. Conclusion

In China, while the Bolar exception has been proposed in the amendment to the Chinese Patent Law, its practice along the line is still in the preliminary stage, allowing application of the Bolar exception within a certain coverage literally. Some circumstances of the Bolar exception in the United States are likely to be put under the traditional experimental use exception to patent infringement or are circumstances of non-infringement not for the production and business purposes in China. In addition, the judges in China are possible to interpret the Bolar exception with their discretion in the future, just as the "production and business purposes" were interpreted in the Sankyo case, and it is now not considered in China to give patentees corresponding compensation by way of extending the term of the patents. It is positive that in China there is still room for considerable development of the Bolar exception both in law and in practice. ■

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[1] Whittemore v. Cutter, 29 F. Cas. 1120 (C.C.D. Mass. 1813).

[2] Sawin v. Guild, 21 F. Cas. 554 (C.C.D. Mass. 1813).

[3] Roche Products, Inc. v. Bolar Pharmaceutical Co. 733 F.2d 858 (Fed. Cir. 1984).

[4] Embrex, Inc. v. Service Engineering Corp.216 F.3d 1343 (Fed.Cir. 2000).

[5] Madey v. Duke University ,307 F.3d 1351 (Fed. Cir. 2002).

[6] 35 U.S.C.§271 (e)(1):"it shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."

[7] Eli Lilly and Co. v. Medtronic, Inc. ,496 U.S. 661（1990).

[8] Abtox, Inc. v. Exitron Corp., 122 F.3d 1019 (Fed. Cir. 1997).

[9] Elan. Transdermal Ltd. v. Cygnus Therapeutics Systems., 24 U.S.P.Q. 2d 1926 (N.D. Cal. 1992).

[10] Intermedics, Inc. v. Ventritex, Inc., 991 F.2d 808 (1993).

[11] Integra Lifesciences I Ltd. v. Merck KGaA., 125 S. Ct. 2372 (2005).

[12] See Brief for the United States as Amicus Curiae Supporting Petitioner, 2003 U.S. Briefs 1237 at 29 (Feb. 22, 2005).

[13] Amgen, Inc. v. International Trade Commission, 519 F.3d 1343 (Fed. Cir. 2008)

[14] See Articles 11 and 63 of the Patent Law of the People's Republic of China as of 2000.

[15] See Chongqing City No.1 Intermediate People's Court's Civil Judgment No. Chongjingchuzi 406/1995.

[16] See the Interpretation of the Patent Law, the Patent Documentation Publishing House, 1994, P.188.

[17] See Yin Xintian (ed), the Interpretation of the New Patent Law as prepared by the Legal Affairs Department of the SIPO, the Intellectual Property Publishing House, 2001.

[18] See the Beijing No.2 Intermediate People's Court's Civil Judgment No. Erzhongminchuzi 04134/2006.

[19] See the Beijing No.2 Intermediate People's Court's Civil Judgment No. Erzhongminchuzi 6026/2005.