

What Can Be Learned from the Case of Viagra Patent Invalidation

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Viagra, a product of the Pfizer Ireland Pharmaceuticals (Pfizer), a world renowned pharmaceutical manufacturer, is a drug having a special effect of treatment of erectile dysfunction (ED). Since it was put on the market, it has been well received by global consumers and drawing extensive attention from the industry. In 2005, the global annual turnover from the sale of Viagra reached \$1.6 billion,¹ taking up about

60% market share of the pharmaceutical of the class in the world.²

On 19 September 2001, publication of the grant of the patent for Viagra triggered dispute of patent invalidation on an unprecedented scale. As many as 13 requesters, including 12 domestic drug manufacturers and a natural person, filed their requests with the Patent Reexamination Board

(PRB) of the State Intellectual Property Office (SIPO) for invalidation of Pfizer's Chinese patent 94192386.X (namely the Viagra patent).

The case went through all the way from the administrative patent invalidation proceedings, to the judicial procedure of first and second instance. On 7 September 2007, the Beijing Higher People's Court rendered the final judgement in the case of administrative dispute over the invalidation of the Viagra patent, and Pfizer was the winner. This important case of dispute, involving a foreign party's IP right, had been going on for six years, and has been closed for the time being. The China Patent Agent (H.K.) Ltd. (CPA), as Pfizer's patent agency, represented Pfizer in all these procedures, including the patent application and invalidation proceedings and the administrative procedure. This case, with complicated circumstances, drew great attention from all sides in and outside China. With the case now settled, we would like to look back at it, and share with you our ideas and experience and all we have learned.

Looking back at the case

On 13 May 1994, the PCT international patent application (PCT/EP94/01580) was filed.

On 8 December 1995, the CPA went through, for Pfizer R&D Corporation, the procedure of the PCT international patent application to enter into the phase in China.

On 20 April 2001, the SIPO issued a Notification on Grant of the Patent, with the claim granted the patent right covering only one specific compound, namely "use of 5-[2-ethoxy-5-(4-methyl-1-piperazinylsulphonyl)-phenyl]-1-methyl-3-n-propyl-1,6-dihydro-7H-pyrazolo[4,3-d] pyrimidin-7-one or a pharmaceutically acceptable salt thereof, or a pharmaceutical composition containing either entity, for the manufacture of a medicament for the curative or prophylactic treatment of erectile dysfunction in a male animal, including man"³. In the description of the patent was recorded the *in vitro* test of the compound of the present invention, "and it was found that they were strongly selective inhibitors to PDE V specific for cGMP." "For example, one particularly preferred compound of the invention has IC₅₀=6.8n MV directed to PDE v enzyme ...". Besides, in the description is also presented the results of the *in vivo* clinical test of said compound, that is "a particularly preferred compound that induces impotency in man of erectile dysfunction".⁴

On 19 September 2001, it was published that Viagra

was granted the patent right, and it was on the same day, Pan Huaping filed a request with the PRB for invalidation of said patent. Later, 12 Chinese drug manufacturers, such as the Tianjin Liangxiang Drug Industry Co., Ltd., also requested, one after another, the PRB to declare the patent invalid, raising the question or doubt of whether said patent was in compliance with the provisions of Article 25, paragraph one; Article 33; Article 26, paragraphs three and four; Article 22, paragraph three of the Patent Law, and Rule 20, paragraph one, of the Implementing Regulations of the Patent Law.

On 3 and 4 September 2002, the PRB held an oral hearing. Since it was a very complicated case involving so many interested parties, the oral hearing lasted two days with hundreds of people present.

On 9 January 2004, the Pfizer Ireland Pharmaceuticals became the patentee in stead of the Pfizer R&D Corporation.

On 5 July 2004, the PRB made the Invalidation Request Examination Decision No. 6228, in which it was held that, with limited test data presented in the description of the patent in suit and for lack of relevance of the data to the compound covered in the claim, it was impossible for those skilled in the art to believe without undue burden that the patented compound could cure or prevent ED of male animals. On account of this, the PRB declared the whole patent in suit invalid on the ground of insufficient disclosure under Article 26, paragraph three, of the Patent Law.

On 18 October 2004, Pfizer brought an administrative action in the Beijing No.1 Intermediate People's Court out of dissatisfaction with said Decision No.6228.

Pfizer held the views mainly as follows:

1) The PRB's standards for "determining" sufficient disclosure were not in compliance with and higher or more demanding than those set forth in the Patent Law, so the application of law was erroneous;

2) The PRB was wrong to have applied the relevant provisions of the newly revised Guidelines for Examination, which went into force on 18 October 2001, that is, later than 19 September 2001, the day on which the patent in suit was granted;

3) The PRB was wrong to have applied Rule 18 of the Implementing Regulations of the Chinese Patent Law. For the PRB, said Rule was applicable because it was one of the specifications of Article 26, paragraph three of the Patent Law. But under the Chinese Patent Law, Rule 18 of the Implementing Regulations thereof was not one of the statutory grounds for invalidation or nullification of a patent. By apply-

ing Rule 18 of the Implementing Regulations of the Patent Law, the PRB unduly adopted the extra or more demanding standards for assessing the validity of the patent in suit;

4) The test data presented in the description were relevant to the claimed compound, and any ordinarily skilled person in the art would believe that the nine more preferred compounds were structurally similar; hence in the absence of evidence to the contrary, it would be believed that they had similar technical effect. As one of the nine more preferred compounds, the claimed compound doubtlessly had the similar effect as described in the description;

5) The IC50 value was tested or measured and the *in vivo* effect determined in a test method commonly used by those ordinarily skilled in the art, and they could test the technical effect of the claimed compound in normal test; and

6) The PRB's decision was contrary to Article 29, paragraph one, and Article 70, paragraph two, of the TRIPS Agreement.

On 30 March 2005, the Beijing No.1 Intermediate People's Court held an open court session to try the case.

On 2 June 2006, the Beijing No.1 Intermediate People's Court made the first-instance judgement⁵, and the PRB lost the lawsuit. While the court accepted the PRB's determination standards,⁶ the court believed that the description of the patent in suit confirmed to them,⁷ and its Decision No.6228 should be reversed.

On 19 June 2006, dissatisfied with the judgement, ten manufactures, including the Tianjin Lianxiang Drug Industry Co., Ltd., appealed to the Beijing Higher People's Court.

On 7 September 2007, the Beijing Higher People's Court rendered the final judgement, establishing that "the PRB's Decision No. 6228, which was made with errors in the ascertainment of the facts and in the application of law provisions, should be reversed; and the first-instance judgement, made with clearly ascertained facts and correct application of the law provisions, should be upheld by this court". The court decided to have rejected the appeal, and maintained the first-instance judgement.⁸

What we have learned from the present case

1. The court system now plays an increasingly important role in the IP protection regime in China.

In the early stage of development of the patent regime in China, the courts had limited experience in dealing with

administrative case of dispute over patent, and judges tended to uphold the PRB's decisions in the absence of sufficient reasons to rebut them. For that matter, once losing in invalidation proceedings, a patentee or an invalidation requester, if a losing party, would be less possible to win in the subsequent judicial procedure. In recent years, however, with the rapid development within the IP regime in China, more and more IP-related cases are handled by courts, and a great contingent of judges are now highly proficient in hearing cases of the kind. With the judges being more capable of independently hearing such cases, the court system are now in a position to play a more notable role within the regime for the protection of the IP rights in China, which, in turn, embodies the increasing amplification and mature of the regime for the IP protection in China.

2. The standards for "determination" of sufficient disclosure of inventions of the second medical use⁹ are accepted by the court, and test data now become more important to patent for inventions made in the field of chemistry.

While the court reversed the PRB's invalidation decision in the judgement of first and second instance, the PRB's standards for making "determination" in the decision were accepted. This has an important impact on the drafting of applications for patent for inventions relating to second medical use.

Several provisions concerning sufficient disclosure of chemical inventions have been incorporated or revised in the SIPO's Guidelines for Examination as of 2006, with more demanding requirements made concerning test data. For example, it is provided therein that:

"In general, the invention of a new use for a known compound requires experimental data in the description to validate the new use and effects thereof; otherwise, the requirement of enablement is not met."¹⁰

"If a person skilled in the art is unable, on the basis of the prior art, to predict that the use and/or its technical effect stated in the invention can be carried out, the description shall sufficiently provide qualitative or quantitative data of experimental tests for the person skilled in the art to be convinced that the technical solution of the invention enables the use to be carried out and/or the effect as expected to be achieved.

For a new pharmaceutical compound or pharmaceutical composition, not only its specific medical use or pharmacological action, but also its effective amount and the method of application shall be described. If a person skilled in the art

is unable, on the basis of the prior art, to predict that the said use or action stated in the invention can be carried out, the qualitative or quantitative data of the laboratory test (including animal test) or clinical test shall be sufficiently provided for the person skilled in the art to be convinced that the technical solution of the invention can solve the technical problem or achieve the technical effect as expected.”¹¹

“As for an invention relating to the use of a chemical product, ... If a person skilled in the art can not predict the use according to the prior art, the description shall sufficiently provide data of experimental tests for a person skilled in the art to be convinced that the product is useful for the said use and can solve the technical problem or achieve the technical effect as expected.”¹²

The revision of the Guidelines for Examination and the examination practice of the SIPO show that the SIPO is more and more stringent about the requirement with regard to test data of chemical inventions. Therefore, as far as an applicant for a patent for a chemical invention is concerned, provision of sufficient test data in the description will be crucial to acquire effective protection of his patent. In the Viagra case, the courts accepted the PRB’s “determination” standards, and it maybe predicted that test data will have an increasingly important role to play in connection with patents for chemical inventions.

3. Relations have been further specified between Rule 18 of the Implementing Regulations of the Patent Law and Article 26, paragraph three of the Patent Law

In the present case, the PRB took the view that Rule 18, paragraph one of the Implementing Regulations of the Patent Law had been formulated to implement Article 26, paragraph three, of the Patent Law, and it may be deemed to be a specification of the latter, an issue that was not touched upon in the two courts’ judgements. But the SIPO in its Guidelines for Examination as of 2006 has addressed the issue and made it clear that “Article 26, paragraph three of the Patent Law and Rule 18 of the Implementing Regulations of the Patent Law have respectively set forth provisions for the substantial content of, and requirements for drafting, the description”;¹³ and “in substantive examination, the description being not conforming to Article 26, paragraph three of the Patent Law due to insufficient disclosure is a ground for rejection under Rule 53 of the Implementing Regulations thereof, the defect belongs to those set forth in Rule 18 of the Implementing Regulations thereof, and the examiner shall not reject the application on this ground. Furthermore, the

grounds for rejection as provided for in Rule 53 do not include the failure of the abstract to meet the requirements.”¹⁴ Here, we can clearly see the SIPO’s view on the relations between Rule 18 of the Implementing Regulations of the Patent Law and Article 26, paragraph three of the Patent Law.

4. The PRB’s decision should be challenged from all perspectives in the administrative procedure.

In handling an administrative lawsuit involving a dispute over patent invalidation, one should not merely depend on rebuttal of the general provisions of the Guidelines for Examination. Rather, it is helpful to challenge PRB’s decision in terms of fact ascertainment, law application and procedural defects or inadequacy since it is sometimes very difficult for one to predict which ground would be accepted by a judge when a case is heard by the court. For that matter, it is not enough just to present the grounds one thinks most convincing.

As is shown in the present case, what is decisive regarding the result of the judgement is not the matter of whether the “determination” standards are lawful or not as extensively debated on in the industry, but the matter of ascertainment of facts, namely, the matter of how the test result is related to the claimed compound. Accordingly, presenting objections from all aspects is very helpful for the judge to comprehensively review a case.

5. Winning understanding and support from the press or media is of considerable importance in the trial of a case.

In the early stage of the case, most public opinions took sides with the domestic drug manufacturers, which put Pfizer at disadvantage even before the court began to hear the case. Along with the progress of the lawsuit, Pfizer gradually won, to an extent, understanding and consensus from the press or media and the public at large by unveiling to them the hard process of making the invention of Viagra, the tremendous efforts and investment made in development of the new medicament, and the role of the IP protection in promoting scientific and technological innovation. All these efforts have created a good social environment for examiners of the PRB and judges to handle the case in an impartial and objective fashion.

6. Teamwork of patent attorneys is indispensable

In the present case, the China Patent Agent (H. K.) Ltd., the leading patent prosecution agency in China, has brought its advantage of teamwork into full play by assigning a great number of highly experienced senior patent attorneys to at-

tend to the prosecution and contentious matters of the case and by working closely with attorneys from other patent agencies and law firms, and teamwork has played a considerable role in the successful prosecution and litigation of the case. ■

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¹ <http://in.news.yahoo.com/070121/137/6bdei.html>, visited on 3 December 2007.

² <http://money.cnn.com/2006/01/15/news/companies/sexdysfunction/index.htm>, visited on 3 December 2007.

³ See the text of the granted patent (Chinese patent CN 94192386.X; and the Patent Grant Publication No. CN1071118C).

⁴ See the text of the disclosed patent application (disclosure No. CN 1124926 A).

⁵ The Beijing No. 1 Intermediate People's Court's Administrative Judgement No. Yizhongxingchuzi 884/2004.

⁶ The court takes the view that "as the characteristics of a patent for an invention of use show, the invention was focused on the medical use. Therefore, in the description of the patent for invention like this must be specified the new use, purpose of use, scope of use, mode of use, method and condition of use, and, as well, was sufficiently disclosed the effect of the product by way of test data, so as to convince those skilled in the art that the invention could achieve its object and the beneficial technical effect. Judging from the characteristics of a patent for a second medical use invention, in the description of a patent of the type should be specified the therapeutically effective amount of the medicament, and method of use, and be described, in detail, its effect of treating the second indication with the data of lab test, animal test and clinical test, to prove that the second use and the known use were obviously different. Otherwise, if according to the description, one could not be convinced that the medicament had achieved, and could achieve said technical effect as stated in the description, those skilled in the art could not reproduce said invention from the perspective of fulfilling the second use of said medicament. The court held accordingly that the PRB's standard on whether the second medical use of a medicament was sufficiently disclosed in the description of the invention patent was due, and was not an improper interpretation of Article 26, paragraph three of the Patent Law. See Section 2.1.3, chapter 2 of Part 2 of the Guidelines for Examination as of 2006.

⁷ The court holds that "the description of the patent in suit presented the scope of the first-level to the fifth-level compounds gradually, and those

skilled in the art could naturally understand that the determination of the preferred level was closely related to the achievement of the object of the invention, so the standards should be consistent, which means the especially preferred individual compounds of the present invention, i.e. the fifth-level compounds, had the best curative effect. In the description of the patent was recorded the *in vitro* test of an especially preferred compound, and it was found that they were strongly selective inhibitors to PDE V specific for cGMP. Besides, in the description was also stated the result of *in vivo* clinical test, i.e. that an especially preferred compound induced the potency of a man suffering from erectile dysfunction. Although there were more than 100 compounds in this level, and it was not specified in the description which compound achieved said effect, it should be noted that normally, the data or test results of a specific compound in the description were derived from a compound of better effect in this level. It was thus made known that the more preferred forth-level compounds had *in vivo* and *in vitro* activities as disclosed in the description. The 9 compounds of the fifth-level compounds, as the most preferred level presented in the description, had similar structures, and their pharmaceutical activities should be similar; hence, it was reasonable for those skilled in the art to learn that the compound of the claim of the patent in suit, as one of the 9 compounds, had the curative effect stated in description, without requiring further inventive effort.

⁸ The Beijing Higher People's Court's Administrative Judgement No. Gaoxingzhongzi 519/2006.

⁹ The PRB holds that "as for an invention relating to the second medical use of a known compound, if a person skilled in the art has to determine said known compound has said second medical use with undue burden according to the technical disclosure of the description and on the basis of existing technical knowledge, said description should be held to have sufficiently disclosed the claimed subject matter." See the PRB's Invalidation Decision No. 6228.

¹⁰ See Section 2.1.3, Chapter 2 of Part 2 of the Guidelines for Examination as of 2006.

¹¹ See Section 3.1, Chapter 10 of Part 2 of the Guidelines for Examination as of 2006.

¹² See Section 2, Chapter 2 of Part 2 of the Guidelines for Examination as of 2006.

¹³ See the last paragraph of Section 2, Chapter 2 of Part 2 of Guidelines for Examination as of 2006.

¹⁴ See Section 3.3, Chapter 10 of Part 2 of Guidelines for Examination as of 2006.