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The Tale of Viagra Patents: Comparative Studies of the Global Challenges in China and Other Countries

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When Pfizer patented its new discovery of second medical use of sildenafil globally for Viagra, it met extensive challenges in many countries, with reasons of, among others, obviousness and insufficient disclosure. As ruled by the courts or patent offices in several countries, patent claims should not go beyond what the inventor disclosed to the public, or it may violate the basic rationale of the patent system and be challenged. The story of the Viagra patent in China was uniquely significant. When the Patent Reexamination Board invalidated the Viagra patent, China received unusual criticism which believably imposed influence upon the judicial decisions. Transnational corporations and their agents were advised to respect and not try to interfere with administrative and judicial procedures in China, which might help establish a fair and efficient judicial system that would benefit both domestic and international parties in a long run. The reasons leading to such extensive failure of the Viagra patents in many countries, especially in a time of enhanced global IP protection are explored in this paper.

Keywords: Intellectual property, patent, Viagra, PCT

Though Pfizer's Viagra had been one star drug on the world pharmaceutical market in the past decade, the general public may not know the first medical use of sildenafil or sildenafil citrate, the active component of Viagra, is for cardiovascular diseases, such as hypertension or angina.[1] However, it was its second medical use for treatment of man's erectile dysfunction (ED) which made it globally well-known. Viagra has contributed accumulatively to Pfizer billions of US dollars of financial income in the past years.[2] Understandably, the market success had been guaranteed by the associated intellectual property rights (IPR), especially patents granted in various countries or regional patent offices, which are members of, among others, TRIPS Agreement, Paris Convention for the Protection of Industrial Property (Paris Convention), and Patent Cooperation Treaty (PCT). As a leading transnational corporation (TNC) specialized in innovative pharmaceuticals, Pfizer had filed patent applications globally for Viagra and had been granted relevant patents by many patent offices. However, the Viagra patents had meanwhile been seriously challenged and invalidated in many countries or regional patent offices, including, e.g., Australia, Canada, United Kingdom (UK), the European Patent Office (EPO), and China. The reasons leading to such extensive failure of the Viagra patents in many countries, especially in a time of enhanced global IP protection are explored in this paper. Furthermore, it would be meaningful to investigate the hotly debated Viagra patent story in China and the related implications. As the biggest developing country with a rather short history of modern patent system (since 1985), China has always been at the receiving end of international criticism for its poor IP enforcement during the past two decades. Meanwhile, being a country with transitional economy, China has been constructing its system of rule of law, including a fair and efficient judicial system. Though the Viagra patent story in China was primarily on the patent issues, it involved multiple aspects deserving a full exploration, such as the potential influence upon domestic judicial system by foreign parties.

This paper reviews the Viagra's global patenting activities and corresponding extensive challenges, and explores the possible reasons. It further investigates the Viagra patent case in China, including criticism, and examines whether the administrative decision was different in essence from that of other countries. Implications of the Viagra patent case for respect of independence of patent and judicial system in China are explored further followed by the conclusion.

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Patenting Globally, being Challenged as well

Patenting Viagra in the World

Pfizer initially filed a patent application with the UK patent office in June 1993. On 13 May 1994, by claiming priority to the UK application, Pfizer filed a PCT application which entered the national phase in the designated thirteen countries (including, e.g., Australia, Canada, China, Japan, Korea, the United States) and EPO (the European Patent Convention then had sixteen member countries). In addition, Pfizer filed directly patent applications in some countries that were not members of PCT in the early 1990s, including some Southern American countries.[3] The mixed situation concerning the Viagra patent application across the world indicated a pre-TRIPS era where unified standards concerning patentable subject matter, prosecution procedures, and the corresponding patent rights were still lacking. Pfizer was finally granted the Viagra patents in many patent offices.

The PCT document for the Viagra patent, with international publication number WO 94/28902 and a title "Pyrazolopyrimidinones for the treatment of impotence", remained the key document for the Viagra patents in many countries. From a hindsight perspective, though the discovery of Viagra as an anti-ED drug or its commercialization could be called a success, the relevant patenting strategy, especially drafting of the specification on which the claims were based, could hardly be deemed so. The patent document, with minor or some modifications in different patent offices, might claim far-reaching monopoly for the newly discovered medical feature, including, among others, (1) the second medical use for treating ED in man or a male animal by trillions of the chemicals with formula (I) (or their pharmaceutically acceptable salts or the relevant pharmaceutical compositions), and in consequence, (2) relevant usage in the manufacture of a medicament for the clinic utility. Regarding numerous chemicals claimed in the Markush form, the specification describes them by five cascading groups, from the most general one with an astronomical number of molecules (claim 1), to a preferred group of compounds (claim 2), a more preferred group (claim 3) and a particularly preferred group (claim 4), and finally the especially preferred individual compounds of the invention with nine specific compounds, the effective ingredient of the Viagra (sildenafil citrate) being the third one (claim 5).

However, description of the invention which is rather abridged, provides "a limited amount of data to explain and support the invention", describes the invention in a manner "somewhat surprisingly", and presents more questions than answers to its target readers skilled in the art.[1] It does not even list any referential publications, whether scientific journal articles or patent documents necessary to introduce both technical background and accurate molecule having claimed utility. It seemed Pfizer hid necessary information from the public. Comparatively, some judicial opinions on the Viagra patents had more detailed scientific knowledge and technical information, such as those of the UK Patents Court and the Federal Court of Australia. Insufficient disclosure had been one of the main reasons leading to the patents being challenged worldwide.

Extensively Challenged

The first challenge the Viagra patent encountered was in UK in 1999 when Lilly ICOS LLC questioned validity of the Viagra patent (EP [UK] 702,555). The Patents Court held that the invention was obvious to a person skilled in the art so the patent was invalid.[1] The court argued, though the inventor found unexpectedly the compounds' usefulness in treating ED, however, in the light of three papers published before its filing date, the invention was not an unexpected discovery, but what each of the papers could lead a person skilled in the art to suspect; it was the Nobel laureate Dr Louis Ignarro and his colleagues who made the groundbreaking work, so that even a general consumer would think about a "nitric oxide pill" for impotence. Therefore, it would be an obvious expectation for a person skilled in the art to have that drug in the pharmaceutical world.[1] Pfizer appealed the ruling to the Court of Appeal but failed, and was disallowed further procedures by the House of Lords in 2002.

At EPO, the Viagra patent (EP 0,702,555) was seriously challenged by a dozen of parties, including Eli Lilly, Merck, Sanofi-Aventis, and Bristol-Myers Squibb (as in Australia, Bayer withdrew due to its settlement with Pfizer). In 2001, the opposition division at EPO revoked the patent based on reasons of lacking an inventive step and having added matter. Pfizer appealed and was dismissed by the Technical Board of Appeal in 2005. By referring to the state of the art, especially the closest prior art embodied in two European patents, EP-A-0463756 and EP-A0526004, the Technical Board of Appeal presented

sound reasoning, including whether there had been in the state of the art certain technical prejudice, and whether the relevant commercial success or scientific awards, could relate to an inventive step.[4]

The Australian Viagra patent (676,571) was challenged by Eli Lilly, concerning claim 10 of the patent which involves inhibitor of cyclic guanosine 3',5'-monophosphate phosphodiesterase (type 5) (cGMP PDE_V) (or its pharmaceutically acceptable salts or pharmaceutical compositions) in a method of oral treatment of ED in man. The trial court found that the claim did not involve an inventive step, and it was not "fairly based on matter disclosed in the specification".[5] Though the Court of Appeal did not have the same opinion regarding inventive step, it did support the conclusion of lack of fair basis of the trial court and thus held invalidation of the claim 10 (ref. 6). Eli Lilly could thus commercialize its own anti-ED drug, Cialis, in Australia.

The Viagra patent in Canada (2,163,446) had claims similar to that of Australia: in addition to claims 1-5 of the PCT patent application, it had two extra ones claiming respectively, two specific compounds selected from the nine especially preferred individual compounds, with claim 7 directed at sildenafil, the third one in the compound list. The challenger of the Viagra patent in Canada was Teva, a generic drug manufacturer based in Israel. The trial court reasoned, "by withholding from the public the identity of the only compound tested and found to work, sildenafil, the patent did not fully describe the invention. Obviously Pfizer made a conscious choice not to disclose identity of the only compound found to work, and left the skilled reader guessing. This is contrary to the statutory requirement to fully disclose the invention."[7] However, it held the patent was valid and the decision was supported by the court for appeal. The Supreme Court of Canada did not accept such a ruling. In a unanimous 7-0 verdict in 2012, it ruled Viagra patent was invalid with a sole reason of insufficient disclosure.[7]

The Supreme Court of Canada argued, while the document included a statement that one of the especially preferred compounds induces penile erection in impotent males, the specification does not disclose the one that works is sildenafil, therefore additional test would be required, and the person skilled in the art would not be able to carry out the invention by using only the instructions contained in the disclosure.[7] The Court held that by not properly disclosing the claimed invention, Pfizer violated its obligation by taking advantage of the patent system, which is governed by a basic rationale, i.e., a patent bargain between an inventor and society: "the inventor is granted exclusive rights for a limited period in exchange for disclosure of the invention so that society can benefit from this knowledge". Logically, "Sufficiency of disclosure lies at the very heart of the patent system, so adequate disclosure in the specification is a precondition for the granting of a patent."[7]

In addition, the Viagra patents (or applications) in Columbia, Venezuela, and South Korea, among others, were invalidated or rejected by reasons such as, obviousness or insufficient disclosure.[8] Comparatively, the Viagra patents in the United States (US), Japan, Spain, Norway, New Zealand, Brazil, and China were kept valid though they had been challenged as well. In the US, when Pfizer sued Lilly in 2002 for infringement of its Viagra patent (USP 6,469,012), USPTO reexamined the patent and revoked its claim 24 (identical to claim 10 of the Australian version), with reasons of having no novelty and non-obviousness.[9] Finally Pfizer gave up suing Lilly for patent infringement, and focused its attention on stopping Teva from making a generic version of its patented product.[10]

Challenging and Being Challenged

It was manifested that when Pfizer tried to pursue patent exclusiveness for its Viagra patent in the world, it met challenges in many countries. In explaining why the Viagra patents had been challenged and defeated worldwide, one may first refer to the actual or potential giant market value. However, though Viagra has been one of the major pharmaceutical products for Pfizer's revenue, it has never been the most profitable drug for the company. As per the report of Pfizer, in 2010-2012, the average revenue by Viagra was about 2 billion US dollars, lower than those of the five major pharmaceuticals: e.g., Lipitor had average revenue of about 8 billion US dollars for the same period, four times as that of Viagra,[2] while the relevant patents had not been badly challenged. Therefore, although the market value may be one of the important or critical incentives for competitors to challenge the Viagra patents, it may not be a primary element leading to their extensive invalidation or revoking worldwide.

Secondly, extensive challenges did not involve issues of public health or patenting higher life forms. As a newly developed pill to treat impotency, the

Viagra was deemed to be a lifestyle drug instead of life-saving one,[11] and in consequence would neither be involved in public health crises and relevant compulsory licence, nor be involved into moral disputes surrounding life patents such as those concerning the Harvard onco-mouse in EPO and Canada.[12,13] It would be rare like the Ministry of Health of Egypt to issue licence to the generic version of Viagra for the interests of poor people.[14]

Thirdly, the Viagra patents had not been challenged due to international political concerns. The patents had been not only invalidated or revoked in UK, Australia, Canada, and EPO (covering the main European Union countries), almost all having been traditional companions of the US as developed countries or members of OECD, but also challenged in China and some Southern American countries as developing countries for identical or similar reasons. This implies that international political considerations or conceptual grouping such as developed or developing counties, or relevant local trade protectionism as such, had not been reasonable interpretations.

Concerning extensive Viagra patents' conflicts, however, it could be said that many countries in which Viagra patents had been essentially challenged do not have any common moral, political or social consideration, but the patent regime which is under the international framework of TRIPS, Paris Convention, and other IP conventions. The challenges Viagra patents had encountered in the world could be easily understood in the context of patent law and its basic rationales. In view of patent law, the Viagra patent(s) really distinguished itself by very broad claim(s) but with a half-hidden description. As reasoned by a justice in the Supreme Court of Canada

> "I would not make too much of the fact that Claim 1 included over 260 quintillion compounds. The practice of cascading claims - although it may, as in this case, result in claims that are overly broad ... However, the public's right to proper disclosure was denied in this case...The disclosure failed to state in clear terms what the invention was. Pfizer gained a benefit from the [Patent] Act - exclusive monopoly rights - while withholding disclosure in spite of its disclosure obligations under the Act. As a matter of policy and sound statutory interpretation, patentees cannot be allowed to game the [patent] system in this way. This, in my view, is the key issue in this appeal."[7]

In doing so, Pfizer was reluctant to disclose necessary information to support its broad claims, not telling readers which molecule had the best effect in treating ED in male animal or man. An expert witness in the federal court of Canada observed, "concealment of identity of the compound tested is nothing short of astounding", and "such an action prevents effective peer review and is poorly viewed in the scientific community".[7] The Supreme Court of Canada spelt it more clearly, "Pfizer had the information needed to disclose useful compound and chose not to release it. Even though Pfizer knew that the effective compound was sildenafil at the time it filed application... It chose a method of drafting that failed clearly to set out what the invention was."[7] As the Court pointed out, Pfizer was playing "hide and seek" games with the public, making it hard to find the exact answer to the technical issue, like searching a needle in the haystack: this kind of practice would surely injure the fundamental rationale of patent law.[7]

Briefly, insufficient disclosure, being not supportive of the corresponding claim(s), had been one of the key reasons for the Viagra patents or applications to be challenged worldwide, leading to judicial or administrative decisions in countries such as Canada (the Supreme Court), Korea,[15] and China (the Patent Reexamination Board). In the language of patent jurisprudence, Pfizer had not fulfilled its obligation as a party to the patent bargain in exchange for market monopoly by its full and clear disclosure of the invention. The extensive failure of the Viagra patents worldwide may imply that the basic rationale of patent system should not be disregarded by any inventor or his assignee that would take advantage of the patent system; or, the patent applications or patents could be challenged by reasons of not meeting the related provisions of patent law accordingly.

Was China Unique or Treated Differently?

Aborted Invalidation of the Viagra Patent in China

China became a member country of PCT since 1 January 1994, and soon after that the Viagra PCT patent application designated China as one of the target countries. After going through the national phase in China it was granted the patent (94192386.X) in 2001. The "claims" of the Viagra patent were modified and were composed of only one claim, i.e., claim 1, the use of sildenafil (or its pharmaceutically acceptable salts or pharmaceutical compositions containing either entity) in manufacturing a medicament for curative or prophylactic treatment of ED in a male animal

including man. Just after that, thirteen parties (one natural person and twelve local pharmaceutical companies) filed applications for invalidation of the patent with the Patent Reexamination Board (PRB) which is under the State Intellectual Property Office of China (SIPO). After a long procedure including a hearing in which the Nobel laureate Louis Ignarro was present as an expert witness, the PRB made a decision in 2004 of invalidating the Viagra patent by reason of insufficient disclosure.[16] Pfizer then sued PRB before the Beijing No.1 Intermediate People's Court, the challenging parties being third parties. The court in 2006 held that the PRB had been at fault in finding the facts, and had been wrong in applying the law, and ruled to revoke the PRB's decision and remanded the case back to PRB for further review and decision.[17] Ten third parties appealed the ruling to the Beijing Higher People's Court and were rejected in 2007 (ref.18). Accordingly, the PRB made a second decision in 2009, holding validity of the Viagra patent in China.[19] Since then there had been no further challenges and Pfizer would probably hold its Viagra patent in China till 2014.

The Patent Law of China has similar provisions like many other countries regarding invention (utility) patents. Article 22 prescribes patentability of an invention for its being granted a patent, including novelty, an inventive step (inventiveness), and industrial application. Article 26 specifies the patent documents and publication shall , *inter alia*, (1) describe clearly and completely the invention so as to enable a person skilled in the art to carry out the invention (para.3), and (2) have the claims, based on the description, stating clearly and concisely the scope of patent protection (para.4). These articles reflect fundamental rationale underlying the patent law or the patent bargain between an inventor and society, i.e., disclosure for monopoly: while an inventor discloses his invention to the public, the patent office, in representing society, may grant him exclusive rights according to the patent law, which could ensure the patentee's corresponding technical and commercial advantages for a limited time. However, an inventor or his assignee should not go beyond the scope of a patent by claiming monopoly on what he did not disclose; or society may pay too high cost for technical advancement, and this may ultimately injure rationale of the patent system and the consequent public welfare connected to it.

At PRB, the reasons employed to argue against validity of the Viagra patent by dozen of challengers include, among others: a method of treatment of human or animal disease, being excluded subject matter (Article 25(3)); having no novelty or an inventive step (Article 22, paras 2 and 3); being not sufficiently disclosed (Article 26, para.3); being not supported by the description (Article 26, para.4). The panel at PRB elected to invalidate the patent by reason of insufficient disclosure. The panel argued, for second medical use of a chemical, if a person skilled in the art, after reading the specification, and in combination with knowledge in the state of the art, still needs creative work to confirm that the chemical has the second medical use, it would be hard to maintain such disclosure is sufficient. In particular, by referring to the limited description in the specification, no given relationship could be established between the test data and the second medical use of the claimed compound. Therefore, it would not be possible to argue that disclosure of the claimed technical solution was sufficient, and the patent did not conform to the patent law of China. With this, the PRB refused to go further to review and comment on other reasons argued by the challengers, including lack of an inventive step and fair support from the specification. [16]

The Beijing No.1 Intermediate People's Court, however, held that although the specification did not specify which compound gives the reported result, in general the data a specification provides are produced by those with better effects. Moreover, as the nine compounds of the especially preferred individual compounds of the invention having similar structures, their pharmacological activities ought to be similar; and, it would be reasonable for a person skilled in the art, without necessity to conduct further creative work, to confirm that the claimed chemical, as one of the nine compounds, has the claimed effect.[17] The same logic had almost been repeated by the Beijing Higher People's Court.[18] Obviously, reasoning of the Intermediate Court can be easily overturned by one's referral to general pharmacological knowledge. For example, contrary to the court's understanding, compounds with similar structures may not have expectedly similar pharmacological effects. For the Viagra patent itself, though all the nine compounds of the same group have similar structures, they do not have similar pharmacological activities at all: there have no evidences to show the other eight compounds have similar anti-ED effect as sildenafil citrate, emphasized by the Supreme Court of Canada. [7]

Criticisms with Pride and Prejudice

While the Viagra patents had been extensively invalidated or revoked during 1999-2012 in many developed countries or patent offices, such as UK, EPO, Australia, and Canada, there did not occur extensive criticisms by Pfizer, the US government or others. For example, when the UK Patents Court invalidated the Viagra patent by reason of obviousness, the ruling even did not "sustain any meaningful criticism for the decision".[20] In Canada, after the Supreme Court's invalidation of the Viagra patent, Pfizer's reaction was only expressing its disappointment, alleging the Supreme Court "accidentally went beyond its jurisdiction" by wholly invalidating its Viagra patent, filing a motion to require the Court's rehearing the case which would be hardly possible, and then having to face coming competition of the generic drug.[10]

However, fallout of temporary invalidation of the Viagra patent in China was a quite different story, in which there manifested huge pride and prejudice among representatives from the US government, business associations, patent attorneys, and international observers. After PRB announced its decision, there were positive comments - as one US lawyer argued, "… despite the rhetoric in the media, Pfizer must also clearly recognize that the China SIPO reexamination decision was neither *per se* unreasonable", nor "out-of-step with the decisions reached by other foreign patent systems".[20] However, on the other side, there were fiercely critical remarks on the administrative decision. The then head of the US-China Business Council in Beijing, expressed his wrath as, "given the current emphasis on improving IPR protection in China, it is quite surprising that a state agency would rule unfavorably... It's surprising to see a lower-level agency making such a ruling, which sends off conflicting signals about China's commitment to improve its IPR environment."[8] The then Deputy US Trade Representative called the Chinese parties' challenging of the Viagra patent a "particularly troubling" example of China's "questionable commitment" to IP rights. An unidentified foreign diplomat even warned that the US and European Union may retaliate with tariffs aimed at China's domestic pharmaceutical industry if Pfizer really lost its Viagra patent.[8]

When looking back almost a decade later, one may be amazed about the attitude of the official representatives and the language they used in criticizing an administrative authority in China. Would the high officials of the US government get rid of the rights of the citizens or companies of China to require PRB to invalidate a patent with legal reasons, or authority of PRB to invalidate a patent by following the patent law, both granted by the domestic laws and international treaties? Could certain citizens or companies' action represent the whole country of China? Or, do the citizens or companies of China need to ask their government what they could do before dealing with issues involving foreign parties? In addition to the demonstrated pride and prejudice, these performances and speeches expressed clearly the officials' ignorance of both liberty of the citizens or companies in China and principles of the international law.

The US high officials were not alone in showing their displeasure. A US patent attorney, after reading only summary of the PRB's decision on invalidation of the Viagra patent, expressed his fury towards the PRB and China. He firstly commented on invalidation of the Viagra patent by the UK courts, "while some might disagree with the outcome; it seems that few would argue that the decision reflects a domestic bias when adjudicating the validity of foreign-owned intellectual property."[21] Then he felt puzzled "how the patent could fail on enablement unless the Chinese language application was very different in scope from the PCT application it derived from."[21] He would then teach the court in Beijing what to do to achieve a judgment that could be in harmonization with international standard, i.e. by following a highly esteemed court. "By substituting the new basis of invalidation, the Court could thus achieve the same result but bring the reasoning more in line with holdings of a well-respected court, the British Patent Court. Indeed, the case made in the UK invalidation proceedings provides a ready-made basis for invalidation of the equivalent Chinese patent while at the same time defusing charge of domestic bias in intellectual property decisions."[21] In addition, China was reminded to take this opportunity seriously "to demonstrate its renewed commitment to the standards of the TRIPS…by providing a firm judicial basis for its legal actions in this arena."[21]

Internationally Comparable or Aberrational?

Though the Viagra patents had been invalidated in many developed countries, no parties in the group of eager criticizers of the PRB's decision, including Pfizer, US governmental officials, representatives of

US-based business associations, certain Western observers or media, had tried reportedly to impose influences upon the relevant administrative or judicial procedures. Their attitude and actions towards China were uniquely distinguished. Was the PRB's invalidation of the Viagra patent so substantially different from those rulings of the courts or patent offices in other countries that China alone deserved such ferocious criticism?

For the many Viagra patents or patent applications with slightly or somewhat modified claim(s) based on almost the same specification (WO 94/28902, or its translated texts), the reasons that had been used to invalidate or revoke them respectively included, among others: (1) obviousness or lack of an inventive step, by the UK Patents Court and the consequent Court of Appeal, EPO (with another reason of having added matter), and the Federal Court of Australia (with an additional reason of lacking fair basis); (2) lack of fair basis, by the Federal Court of Australia; and (3) insufficient disclosure, by the Supreme Court of Canada, and the PRB of China. In addition, the Viagra patents or patent applications in Columbia, Venezuela, and South Korea were invalidated or rejected for identical or similar reasons.[8] Though with different causes or directing to different claims, all the decisions of invalidation of the Viagra patents or rejection of the patent applications by different courts or patent offices could be comprehended and accepted, due to the basic principle of independence of patent prescribed by the Paris Convention (Article 4bis). An international IP scholar interpreted the cases accordingly: "the invalidations are understandable, as it is unrealistic to assume that patent offices and courts in other countries will uphold a patent merely because it is valid in the US. Due to philosophical differences and diverging local conditions, decision-makers sometimes come to different conclusions even when they apply identical laws to identical facts."[22]

By comparison of the decisions on validity of the Viagra patents in different countries or patent offices, one could infer logically there is no justifiable misapprehension, misinterpretation, or misjudgment within the PRB decision. Specifically, the claims that had been invalidated by the Supreme Court of Canada (claim 7 of CA 2,163,446) and PRB of China (claim 1 of CN 94192386.X), respectively, were almost the same, which involves essentially the use of the compound 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, in manufacturing a medicament for curative or prophylactic treatment of ED in a male animal including man. Correspondingly, the reasons used by the Supreme Court of Canada and PRB to invalidate the claims were almost the same, i.e., insufficient disclosure by the specifications. Surely there were differences between the rulings of the two organizations: the decision of PRB was furnished with lots of technical terms and evidences, while the ruling of the Supreme Court of Canada was far better drafted and modified, full of legal reasoning and sound argument on basic rationale of the patent law. It could be said, however, the PRB's invalidation of the Viagra patent had been well justified under the current international patent law framework, being internationally comparable and acceptable, but not aberrational that should be denounced fiercely. "Regardless, while Pfizer's second use patent for Viagra has suffered flawed losses in other developing countries, in China, SIPO's decision to invalidate was reasonably founded."[15]

IP scholars further argued that the challenging activities against the Viagra patent in China incurred by the local companies may indicate progressive growing up of the market economy in China, because the domestic enterprise was learning to do business by using IP laws legally, instead of simply infringing patent rights of third parties by ignorance of the law.[23] "Rather than criticize China's legal challenge of Pfizer's patent… the international community should recognize this event as the beginning of a new phase in the promise of IPR protection in China."[20] "That is a great improvement", and "what these critics failed to realize, or at least acknowledge, was that SIPO's decision was exactly what IPR holders should expect in a country making transition to full compliance with the WTO agreements."[22] Some local or international patent attorneys held similar views as well, regarding the local companies' challenges being indicator of their "using the patent system as a strategic business tool".[20]

Taking into consideration the unusual criticisms China had received solely due to the PRB's decision, one could infer reasonably that China was treated differently with an isolated benchmark by the international criticizers.

Implications of the Viagra Patent Case in China: Independence of Patent and Judicial Procedures

According to the Patent Law of China (Article 46, para.2), if an involved party is not satisfied with a PRB's decision, it can bring a case against PRB before a court with jurisdiction, i.e., the Beijing No.1 Intermediate People's Court, for judicial remedies. After analysing the PRB decision and the Viagra patents' experience of being challenged in other countries, an attorney in the US predicted a likely outcome in China could be that the Intermediate Court would probably support the PRB's invalidation of the Viagra patent.[20] Even an acute criticizer would hint the court may support the PRB decision, if it would be clever enough, following the UK Patents Court to alter the underlying ground to be obviousness which may not risk China's international fame for IP commitment.[21] Quite amazingly, to the contrary, the trial court made a dramatic turn and revoked PRB's decision with obviously leaky reasoning. Had there been no external interference, fancifully, the court might not have held such a technically and legally irrational judicial decision. This concerns the issue of judicial independence.

Admittedly, judicial independence was far from fairly esconced in China, due to institutional deficiencies which need to be improved by reform expected for decades.[24,25] The perplexity thereof was commented by a well-known legal scholar, Professor Chen Xingliang at the Law School of Peking University,

> "However, we shall see, for our society at present, judicial independence is still a remote target. Due to certain institutional check, we have been far away from judicial independence. The judicial reform we have been carrying out now is only to establish a judicial system for judicial independence, as our judicial activities have still been interfered from the institutions of the Party and Administration and from the wills of the leaders, which prevent our judicial system from constructing a crime strictly in accordance with the law."[26]

For contemporary China, since beginning of 1980s, a fair and efficient judicial system has always been an anticipated target to struggle for, in which the process was disturbed repeatedly by various elements. As illustrated by Professor Chen, the hardest barriers have been fixed and maintained by the stakeholders that remained interested parties of both politics and economy within the country. It would be definitely most important for the concerned parties or institutions to learn to respect earnestly the laws and legal procedures, and not try to manipulate or disturb judicial decisions for reasons not prescribed in law and by law, or the country would see hardly any hope of a fair and efficient judicial system.

It has been observed that some TNCs have been interfering with the judicial procedures in China since 1990s. Some, if not many, TNCs, together with representatives from their governmental agencies or business associations, criticized China's lack of judicial independence and other facilities and therefore would not recognize its status of market economy. This is understandable, for China as transitional economy has intrinsic deficiencies in social governance of which the general Chinese people may have keener awareness. However, on the other hand, once their economic interest is involved, the TNCs may not hesitate to bring about impact upon judicial or administrative procedures by economic or political means. Regarding the Viagra patent case in China, the procedures lasted for about eight years (with 3 years at PRB for its first decision, 2 years in Beijing No.1 Intermediate People's Court, 1 year in Beijing Higher People's Court, and 2 years at PRB for its second decision), a much longer duration than those of the general cases. During this stretched period, numerous events took place, supported by key roles of high-level representatives from the US government, the US business associations, and various international observers that poured criticisms or blames on China, calling its missing international obligations and commitment as such.[15,27]

During the invalidation procedure of the Viagra patent in China since 2001, the US governmental officials had repeatedly raised the issue with relevant authorities in China, "calling it a test of their commitment to international trade rules".[28] "Almost every high-ranking US official visiting China has brought up this issue when they met their Chinese counterpart",[29] who might have to pass the diplomatic concern or pressure on to the relevant administrative or judicial departments through undisclosed channels. In more occasions, the US governmental representatives might elect to criticize directly administrative decision of PRB, in the hope of steering the court to make a rewarding decision. In doing so, they may forget or put aside the basic principles of international law and international

relations. Soon after PRB announced its decision of invalidating the Viagra patent, the US Embassy in Beijing issued "a statement criticizing the decision by the Board and warning that this decision may deter foreign enterprises from entering Chinese market for the concern of lack of IP protection".[30] A spokesman for the US Trade Representative's Office said in the same direct way, "it's difficult not to view this case within a pattern of intellectual property infringement."[28] These diplomatic activities actually politicized domestic legal issues.

Business associations were more aggressive in criticizing the administrative decision. A high-level manager at the Pharmaceutical Research and Manufacturers Association (PhRMA) said the PRB's determination sent a worrying message about China's commitment to protecting the IP rights, which might bring negative impact on further investment in China.[27] The American Chamber of Commerce in China stated that the decision caused great concern in not only pharmaceutical industry but also entire business community. Certain Western medium also displayed its tendency clearly: "…China decided to ignore market principles, its own World Trade Organization commitments and the long-term interests of its people by overturning the drug's patent."[31]

Ironically, with the judgment of the Intermediate Court which kept alive the Viagra patent in China, international comments were sharply turned. Seemingly the Viagra patent case could be a touchstone to test the TNCs' views towards patent practices in China. When the Viagra patent traveled from PRB to the Intermediate Court, the level of patent system in China developed amazingly from "a historical retrogression" to a level marked by "a milestone judgment".[32] Development of patent protection in China could be so easy and simple, with a single indicator to see whether it supports or serves commercial advantages of a TNC in the local market. Expectedly, for the sharp switch of comments on the Viagra patent case in China by the relevant parties, some Chinese IP scholars did not agree. For example, Professor Li Shunde, the then Executive Director of the IP Law Research Center in the Chinese Academy of Social Sciences, argued that one should not link a certain case with the level of IP protection in China; similarly, the Viagra patent was also invalidated in UK, could one say that the patent protection was rather low there?[33]

The intensive disputes regarding the Viagra patent in China might remind the public surviving of a century-long tradition of enjoying super-national treatment by foreigners in China since the Opium Wars in the middle of 19th century when unilateral exterritoriality was established. Though relevant legal instruments were finally abolished in 1940s, substantial super-national treatment has continued to survive in the country till the contemporary time, in which many issues concerning foreign parties have been paid more attentions or granted more advantages than those involving domestic ones. Among others, super-national treatment had also been displayed in the field of IP law. For example, according to the China-US Memorandum of Understanding on the Protection of Intellectual Property (1992), in addition to the necessary revision of its patent law to grant patent protection for chemical and pharmaceutical inventions, China needed to provide administrative protection reversely to those pharmaceutical and agricultural chemical products having been granted patents in the US and having not been marketed in China in 1988-1992 (Article 2). A former director of the Department of Treaty and Law of SIPO still felt angry with this kind of arrangement two decades later.[34] In the field of copyright law, super-national treatment had even been embodied more extensively, once granting more rights and supplying more convenient procedures to foreign parties.[35]

The super-national treatment might have led to expectation of foreigners, especially the TNCs from the US or other highly developed countries, to be granted higher status than citizens or companies of China. Due to diplomatic skills, the TNCs would first solve a specific issue in hand in a friendlier manner, such as visiting relevant authorities, meeting with leaders of the government, expressing their deep concerns, and showing their potential interest to invest more in China. As in the Viagra patent case, after numerous expressions of their deep concerns by representatives of the US government or trade associations, there was an unexpected result given by PRB: they expressed their desperation, and predicted the case's potential adverse impacts upon future economic or diplomatic affairs.[20] However, when the courts supported the Viagra patent finally by revoking the PRB's decision, the eager criticizers saw China again a fair place for trade and investment. The Viagra patent case illustrated a full story of the long lasting tradition of supra-national treatment in China, even if in the 21st century.

Nevertheless, China has been managing in recent years to get rid of such vestiges of both half-

colonization during 1840s-1940s and a less-developed economy before the 21st century. For example, in December 2010, in order to create a fair tax system for both domestic and foreign companies, China began to levy additional taxes on foreign companies, letting them be treated equally with the domestic ones, indicating an end of the supra-national treatment on taxing which lasted for decades. As commented by a representative from the European Chamber of Commerce in China and rephrased by the *China Daily*, "that foreign companies are gradually being treated the same as their local counterparts, sending a strong signal that China's investment environment and policies are maturing…"[36]

Patents are intrinsically of nation-based rights, granted and protected by domestic laws which may need to be in compliance with international conventions. However, once the laws of a country meet with standards of the conventions, all the issues or cases will essentially fall within jurisdiction of the domestic laws, and will be under discretion of an administration or a court. If a party is not satisfied with an administrative or judicial decision, it could appeal for legal remedies according to the domestic laws of the country. This could help nurture a healthy market useful for both fair competitions and social welfare.

Furthermore, if a foreign party deems certain domestic law violating the country's international obligation, the party may require or lobby its own government to complain in WTO or other international forums for a resolution, as was done by the US in 2007, complaining against China for its enforcement of IP rights with the dispute settlement understanding in WTO. Trying to interfere with domestic administrative or judicial procedures would not be an advisable choice, as observed in the Viagra patent case in China. Anyway, China has constructed its modern patent regime in line with TRIPS and other international conventions; any party that would take advantage of the patent system will meanwhile have to meet its obligations prescribed by the patent law, whether it is a domestic company, or a TNC.

Conclusion

While Pfizer patented its discovery of second medical use of sildenafil globally, it encountered extensive challenges, majority of which concerned deficiencies with the invention itself and patenting strategy, including obviousness and insufficient disclosure. Taking into consideration its giant market value, professional patent agents may be confused by the risky patenting strategy Pfizer adopted. For dominating extensively on the anti-impotency market, Pfizer hid information necessary for the person skilled in the art to carry out the invention. While trying to use the patent system smartly, Pfizer had to face numerous challenges in many countries, and in consequence lost truly billions of US dollars. For anyone who would take advantage of the patent system, the lesson to be learned could be, among others, a party should not play games with the patent law, and should not violate the fundamental rationale of the patent system. At any time when one party would challenge the patent law, it could be challenged back as seriously as the challenging itself.

From the Viagra patent story in China, together with those in other countries, meaningful implications may be inferred. Though in a time of globalization, the rule of independence of patent still remains; an administration or a court in a member country, by following domestic laws, should be free to have its discretion in deciding cases, including those involving foreign parties. Politicizing domestic legal issues for maximization of individual parties' temporary economic advantages in China, as Pfizer, the US governmental representatives and others did in the Viagra patent case, may worsen the situation and make it a much harder way for China to establish a fair and efficient judicial system, which would benefit both domestic and foreign parties in a long run.

Regarding the long-lasting supra-national treatment, for one day such foreign superiority (including such expectation and being so treated) or foreign interference exists, an independent judicial system will not be able to complete its construction. It would be advisable for foreign parties, especially TNCs, together with their governmental or business agents, to learn to respect administrative and judicial procedures and decisions in China, even if the relevant rulings may be unfavourable for their market advantages as expected. Equally, foreign companies, as their domestic counterparts, are advised to pursue market advantages by following the domestic laws of China. Nevertheless, an administrative authority or a court of any level in China shall be obliged to follow and interpret the law according to the law itself, and not political correctness, whether domestically or internationally.

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