



**On Invalidation of the Patent “Pharmaceutical Composition Comprising Valsartan  
and NEP Inhibitors” No. 201110029600.7**

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On September 15, 2017, the Reexamination Board performed oral proceedings for request for invalidation No. 4W105696. This is the fifth case included in the activity of public hearings for important cases conducted by the Reexamination Board. It relates to the invention patent numbered 201110029600.7, of which the title is “Pharmaceutical Composition Comprising Valsartan and NEP Inhibitors” and the patentee is NOVARTIS AG. The requester for invalidation is Jinliang DAI.

This case involves significant economic interests and incurs dramatic social influence. Therefore, the Reexamination Board formed a collegial panel consisting of five persons to perform public hearings.

The major dispute of the two parties involved in this case includes the following aspects: based on the experimentation disclosed in the description of the present patent and the evidences submitted by both parties, whether the description provides sufficient disclosure, whether claim 1 possesses inventiveness, what the relation is between fulfilling the requirement of sufficient disclosure and fulfilling the requirement of inventiveness, whether the prior art teaches to combine Sacubitril with Valsartan, whether the technical effect obtained by the foresaid combination exceeds reasonable expectation of one skilled in the art and the conditions to be met by the unexpected technical effect, etc..

It is known that according to the provisions of *Guidelines for Patent Examination*, for inventions in chemical field, the technical effect can be hardly expected, and thus, the invention always need to be proved by experimental results. For new pharmaceutical compositions, the specific medical use or pharmacological effect should be described, as well as the effective amount and usage. If one skilled in the art cannot predict that the invention has the medical use or pharmacological effect, there should be



sufficiently described the qualitative or quantitative data of laboratory test (including animal test) or clinical trial so that it is proved for one skilled in the art that the technical solution of the present invention is capable of addressing the technical problem to be solved or achieving the expected technical effect.

In view of the essence of the patent system, patent aims to sufficiently disclose a technical solution in exchange for market exclusivity protected under the national laws. As the term of market exclusivity based on a patent starts from the application date, it is required that the technical solution is sufficiently disclosed in the application document submitted by the applicant on the application date so that the public is enabled to sufficiently acquire the associated contents of the technical solution. Experimental data, as an important component of patent application document, effectively helps the public to sufficiently understand the technical solution disclosed in the patent. However, if the standard of experimental proof is not regulated, it will be inevitable that the applicant intentionally or unintentionally omits some technical details in the application document filed on the application date, which makes it difficult for the public to acquire sufficient technical information in the application document filed on the application date.

As for this case, the pharmaceutical compositions involved in this case include Sacubitril and Valsartan, both being an optional compound in this field for treating hypertension. Therefore, to determine whether the pharmaceutical compositions of the present invention possess inventiveness, major consideration should be given to the problem whether the pharmaceutical compositions achieve an unexpected technical effect. According to the disclosure of the description of the present invention, two biological models are adopted to verify the technical effect, namely SHR and DOCA-salt rats. The description further discloses in paragraph [0063] that “the results shows that the composition of the present disclosure has unexpected therapeutic effect”. However, the description does not disclose the specific experimental results.

Generally, any related technical content that cannot be obtained by one skilled in the art from the prior art should be disclosed in the description. For example, if a technical effect is hard for one skilled in the



art to expect based on the prior art, foresaid technical effect should be verified in the description, accompanied with specific experimental effects. As for the present case, although the patent claims to “have unexpected therapeutic effect”, the description does not disclose specific experimental results to verify the technical effect. In this case, is it permitted to verify the technical effect by additional experimental data? According to *Guidelines for Patent Examination*, it is not prohibited to submit additional experimental data for proving a technical effect after the application date. The amended *Guidelines for Patent Examination* provides that “where additional experimental data is submitted later than the application date, the examiner shall perform an examination on the additional experimental data; the technical effect verified by the additional experimental data shall be acquirable for one skilled in the art according to the contents disclosed in the patent application”.

Therefore, whether the additional experimental data is accepted is determined by the matter whether the technical effect verified by the additional experimental data can be acquired by one skilled in the art according to the contents disclosed in the patent application. The reason why the scope of additional experimental data as proof is limited includes two aspects. On one hand, in view of the essence of the patent system, patent aims to sufficiently disclose a technical solution in exchange for market exclusivity protected under the national laws. As the term of market exclusivity based on a patent starts from the application date, it is required that the technical solution is sufficiently disclosed in the application document submitted by the applicant on the application date so that the public is enabled to sufficiently acquire the associated contents of the technical solution. On the other hand, additional experimental proof is, fundamentally, evidence. It is the entitlement of an involved party to submit evidence that effectively helps the involved party verify the associated technical effect. Thus, the right of the involved party to submit additional experimental data should not be deprived. Whereas, if the standard of experimental proof is not regulated, it will be inevitable that the applicant intentionally or unintentionally omits some technical details in the application document filed on the application date, which makes it difficult for the public to acquire sufficient technical information in the application document filed on the application date and thus, hard to represent the technical solution disclosed by the invention.



Nevertheless, there still exists controversy in the patent examination and judicial practice over what kind of technical effect can be deemed as “acquirable for one skilled in the art according to the contents disclosed in the patent application”. For example, in this case, the following problems arise: i. whether the technical effect merely described in words can be deemed as “acquirable for one skilled in the art according to the contents disclosed in the patent application”; ii. whether the additional experimental data should be obtained under completely the same experimental conditions (e.g., using the same animal models) as those described in the description; iii. whether there is a need for the additional experimental data to prove that the whole protection scope of the claims has an unexpected technical effect; iv. where the additional experimental data is provided solely by the patentee, the authenticity of which is not recognized by the requester, and yet the request cannot provide counterevidence, whether foresaid additional experimental data can be used as effective evidence for the final decision.

With regard to the above issues, through this case, the Reexamination Board made the following comments in the subsequent Decision of Examination: “**conclusive assertion**”, without experimental data as proof, cannot be deemed as a technical effect that can be obtained by one skilled in the art from the original description. On this basis, the collegial panel further determined that the additional experimental proof submitted later than the application date, if merely submitted for proving the “conclusive assertion” in the original description, will not be accepted. Eventually, the patent involved in this case is declared invalid wholly due to defects in the experimental data.

In addition, in terms of the presentation manner of the claims, this case triggers the following thoughts. According to the description, this case relates to pharmaceutical compositions for treating multiple deceases including hypertension. Therefore, the involved patent takes the presentation manner of non-limiting compositions, which complies with relevant provisions of *Guidelines for Patent Examination*. Moreover, the patentee holds the opinion that the key of the present invention is to choose the components in the compositions and it is unnecessary to limit the content of each component, which also complies with relevant provisions of *Guidelines for Patent Examination*. However, the description merely discloses the experimentation relating to the treatment of hypertension; and it is difficult to prove with the additional experimental data that the unexpected technical effect can be obtained by the



compositions with random content of each component. In view of the above, it is a feasible option to incorporate features of definition by use into the claims and adding dependent claims defining various content ranges, so as to benefit to patent stability.

### **My Impression of Silicon Valley**

#### **-Brief summary of the half-year overseas study experience**

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For me, a graduate majored in Electronic and Information Engineering, the Silicon Valley stretching from the south of San Francisco to San Jose on the other side of the Pacific (Californians also call it as “the Bay Area” since it starts from San Francisco Bay), sounds like a legend. In the spring of 2015, I once spent a week to visit clients along the coastline from Silicon Valley to San Diego in the Southern California, and deeply felt the cultural shock. One week as short as it was, it did not allow me to fully understand differences not to mention mitigate them.

In August, 2017, thanks to the trust and support from the colleagues and leaders in the firm, I got the chance to study at Santa Clara University School of Law for LL.M which ranks top 5 in the US in terms of the IP major. The first semester was gone in a flash, but it enabled me to have a fully immersed experience of studying and living in the Bay Area.

#### **I. The soul of Technology**



Not only in the Bay Area, as south as the San Diego in the frontier of the US and Mexico, and as north as the Seattle in the frontier the US and Canada, the prosperous development of technology field in the west coastline of US is making technology root and spread, becoming the hot spot in the daily life of the whole society. It is even harder to tell whether people's zealousness about technology propels the prosperity of companies, or the companies' prosperity propels people's attention to technology.

When I had a lunch with several patent attorneys and in-house counsels in Seattle in 2013, the conversation was persistently centered on the latest product of Apple, Microsoft and Google as well as its functions, including the novel concepts and the patentable features. Outdated in electronic products as I was, I found it was hard to make any comment.

In 2017, I got an Uber to San Jose, the heart of Silicon Valley, to visit client upon finishing auditing a venture contest in the conference center of Santa Clara, the chatty driver is a native of San Jose. When I told him about the program of the roadshow in the venture contest, he constantly said "cool", and then asked me about my impression about Silicon Valley. I couldn't help feeling that the normal two floor buildings along the road hold the world renowned technology brands. Everyone here talks about technology. For example, in terms of the unmanned vehicle, it is a hot topic in the Bay Area. But when I mentioned it to a senior patent partner from East coast, he responded by constantly shaking his head: "I will never sit on that thing. Is there anyone who really dares to sit on it?", which formed a shape contrast. The driver of the Uber nodded: "Definitely, here we have nothing but technology. Everyone here loves technology. It needs time to accept the newest concept which is also from the west to the east."

In the public event gathering websites like Meetup and Eventbrite, various small scale gatherings about AI, blockchain and Fintech fill in the calendar. All technical companies are willing to provide venues or even sponsor to hold such kinds of events during lunch time. The engineers all voluntarily participate, and draw the inspiration of research from the exchanges. Since the technology is advancing at an extremely fast speed, people all worry to fall behind of the fast changing knowledge universe, so



everyone is willing to share and exchange. These kinds of gatherings are full of men and women at all ages. When you involve, you would hardly forget the middle aged female engineer you talked with has two or three kids at home and bears several roles. It seems that exchanging with peers after work, updating knowledge and sharing information has become an essential link in the technology ecology of Silicon Valley.

What impressed me the most is still the universality of interdisciplinary exchanges in the Bay Area. When I just came to Saint Clara, the first lecture I heard about VR was organized by the school of arts and history of Santa Clara University, where Nvidia, the leading company in the field of VR, was invited to give a lecture in the teaching building of the school of arts, which surprised me completely. But after finishing the lecture, I fully understood, that, from the perspective of Nvidia, the promotion of new technology accounts on the building of the whole system, which is not only related to a bunch of engineers. The young fellows make contribution to the multiple applications of VR in the field of movies and design. And these passionate young fellows might intrigue new sparks in the R&D of VR. The key to the puzzles of R&D faced by engineers probably hide in the concept which is well known for designer, who knows?

## **II. The implication of law**

I have heard of the soundness of the legislation of the US, the high income and social status of attorneys since very young, but it is still better to see than to hear when I came to the Bay Area. The legal circle of the US is truly a healthy and positive ecology.

The degree of JD and the success in the Bar examination of California State are the two keys if you want to practice law in California State. Obtaining a JD degree will at least cost three years and hundreds thousands of dollars, and the GPA of the JD will almost decide whether you can find a good job after graduation. The Bar examination of California State is seen as a serious concern by students for its multiple subjects and subjective items as well as the low passing rate. But since there is no other ways, all the students have to "kill themselves" in order to achieve good grades in the examination



preparation season. Given the prior huge investment and the subsequent pressure to find a job, seldom students will treat it lightly. A senior student of JD in my school became my mentor after the matching in the association. Like me, he also has a background of electronic engineering. He was born in a family of attorneys, and his uncle is a senior patent attorney in Qualcomm. Because of his passion about IP and his excellent GPA, he was hired as trainee by a top law firm since his second year, working more than 30 hours per week while continuing his study at the same time. He mentioned to me that it was nothing at all for him to work or study for more than continuous 10 hours a day. He would get excited and forget to sleep or eat when he meets a new research program to be studied.

The law firms of the US treat the talents as their lives, and do their best to attract the excellent graduates from law schools. They often have partners who are responsible for maintaining the relationship with law schools and talent recruitment. The leading law firms are more than delighted to give practical speeches with free meals in law schools, voluntarily helping graduates drafting resume and improving interview skills, or co-organizing other events with alumni association of law schools, dispensing souvenirs with their firms' logo or even organizing the lottery. The gift could be Amazon Bluetooth speaker, Starbucks cash card, Starbucks or pizza knives, but they all have a firm's logo. The purpose is obviously to make the firm known by students before graduation and build their reputations, which will benefit their talent recruitment. The basic annual salary for those who enter the Top 100 law firms after graduation is about 180,000 dollars, and for those senior attorneys, the year-end bonus could be as high as six month salary. Many years ago, the third party investigation institute disclosed the income of the most excellent attorneys, so it is accessible for everyone to know the income of each position. Once a law firm firstly arise the income above the average level, the other law firms have nothing to do but to follow, rather than taking the risks of losing their talents. So the chain of high investment and high return truly enables the legal profession full of the top talents who survived in the fierce education competition. And the attorneys of the US will treat their reputation as lives.

The judges of the US enjoy a very high social status; and they can be classified into the judges of federal court and state court, according to the different appliance of law, where the federal judges enjoy a superior position. Most of the judges are excellent attorneys with many years practicing experience.





Since the patent law belongs to federal laws, accordingly the court to handle patent cases is also the federal court. To make sure of the impartiality, the system of life tenure is adopted to the federal judges who will be well paid and don't need to worry about retirement. For the students of law schools, becoming a clerk of federal judges would a great honor. Also, they could know how the judges think when they judge the cases; consequently they will be hired with high salary by law firms. Contrary to what happens in China where the law firms will hire the judges and pay them well, I never hear the federal judges resign to join a law firm.

The legal profession of the US has strict regulations or professional ethics, and extremely strict standards and punishment have been set up to regulate the behaviors of attorneys. In the past when we communicated with the US clients, we often took an example happened in 2005 when our firm just established to demonstrate that we honestly tell the clients that we were out of capacity to handle the amount of cases the client planned to entrust us rather than telling a lie. This definitely is rare to be seen in the legal environment of Asia, and it truly brought us the client's accomplishment and trust. However, for the US attorneys, telling the truth to clients when they are out of capacity to handle the case with high quality is not only a basic requirement in their professional regulations, but also belongs to professional ethics that everyone has to follow.

Once they violate professional ethics, under such circumstance, at best, they will be interviewed by the legal practice committee of California State, recorded into the file of legal practice which is public online, forming a known stain, or at worst, they will be ended up with revoked license and the firm will be fined with millions of dollars and go bankruptcy. Given you have invested hundreds thousands of dollars tuition, almost killed yourself to pass the bar examination of California State, get hundred thousand salary per year with an annual increase after graduation, work with elites, how would you treat your career? Will you take the career you have fight for hardly as a joke without any cherishment, lose the qualification for cheating client for the sake of small profit, ruin your career which is well paid, and put a disgrace to the elite field? Apparently, it doesn't make sense for a reasonable person to do so in the ecology environment of the US legal profession.



Compared with the US, the legal environment of China is far from well regulated. When Chinese companies encountered “black agency” and irrevocably lost their patent assets, the self-protection consciousness of companies often leads to their more cautious attitudes in the future cooperation with patent agencies and oppressive clause in the course of assigning agreements. And that the foreign law firms which help them handling foreign legal matters is far away, expensive and invisible, worry them more. Considering the huge difference of China and Western legal ecology, the fact which is hard to image but truly exists is that, many questions and challenges from untrusty about foreign law firms falls into their basic professional ethics scope, which never occurred to them and even would be regarded as insulting. The shock incurred in the communication with foreign law firms roots in the unsoundness of Chinese legal environment. The setting up and enforcement of professional regulations of Chinese law circle; the improvement of the professional images accounts on the joint efforts of legal practitioner of China with conscientiousness.

### **III. Fighting for equality**

The Silicon Valley is not always on the bright side. Even inside the Silicon Valley, the most criticized problem is the so called “fraternity culture”, or put it in a simple way, the elite culture dominated by male. The proportion remains low for female and minority group becoming executives in technology companies and law firms.

Fortunately, the minority get together to gain strength. Many successful females and Asians who become executives in companies are happy to get together to change the current situation, and proactively to advance the equality of minority group. When I attended the activities of Asian legal association and female club of technology and law, I found many successful females cultivate young female law practitioners after work in the hope of changing the current situation of fraternity domination from the next generation. With the joint efforts of female General Counsel in technology companies, more and more companies request the law firms to report the gender proportion of their employees when hiring a law firm to make sure the equal working opportunities are given to females and minority. Once, three male partners of a patent law firm told me that one of their clients requested



them to transfer all their cases to a patent law firm managed by a female CEO, because the client wants to support a balanced development of technical legal field in the Bay Area. And more and more Asian in-house get together and devote themselves into the promotion of Asian's career development. Before long, the celebration for the 100<sup>th</sup> female GC in the Bay Area was held. The situation of Asian burying head and working but their voice were unheard and unrepresented might be under changes.

What I mentioned just now, I never heard about them in China before. It is said that one of the big Chinese patent law firms boasts of their policy of not hiring female employees. So it is surprised and amazed for me to see the successful predecessors in legal field committed themselves to the new undertakings of improving the career ecology and various kinds of voluntary actives, after their busy work. Just as a Chinese GG mentioned in the GG round table of Chinese attorneys in the Bay Area association: hopefully everybody does not always think about how to get, but rather think about what can you give to this industry. And this is very thought provoking.

The soul of technology, the implication of law and the fighting for equality, many concepts in my mind are freshened within a short semester in Silicon Valley and brings me shock. I hope I could finish my study in 2018 and apply what I have learnt, and discuss with you more when I am back to the office.