“Unofficial” CN Orange Book user guide for pharmaceutical patents

Abstract
The equivalence of the US Orange Book in China, the “CN Orange Book” has been operating since 29 June 2021. This “CN Orange Book” is a mountain full of treasures, for example clear indication on what claim is covering which subject matter in a particular drug patent. This “unofficial” user guide aims to provide foreigners information on how to navigate this “CN Orange Book”, which operates in Chinese.
In the US, the Orange Book is a publication from the US FDA that identifies drug products with marketing approval from the FDA and related patent and exclusivity information. Information in the Orange Book could be used in actions under the Hatch-Waxman Act, which allows a patentee to file an artificial act of infringement that allows the drug innovator to file suit before the generic drug is commercialized, such that the drug marketing approval process of the generic drug at the US FDA could be suspended.

China is required to introduce a similar system under the trade agreements signed with the US in January 2021. I have been following this since then, and have several articles and posts on this topic. Recently, this “CN Orange Book” (official name: China list drugs patent information registration platform) has become officially online on 29 June 2021, with many developments thereafter, and I have received many questions on how to use this. This motivates me to write this “unofficial” user guide, mainly for foreign users. This user guide may need updates periodically as things are changing too fast in China.

The equivalence of the US FDA in China is the China National Medical Products Administration, the NMPA.
Available to anyone, but could only search in Chinese

The “CN Orange Book” is available at [https://zldj.cde.org.cn/home](https://zldj.cde.org.cn/home). Anyone can access information therein. Below is a screen shot of the first page showing different functions thereon:
For searching drug patent information already registered, the information is divided into three tabs, each respectively directed to Chinese medicine, chemical drug, and biological drugs as shown below (with the tab of chemical drugs chosen):

Searches could be done and directed to the drug name, the format of the drug, dosage, and the drug marketing number at the NMPA. Mostly the name of the drug is used. Partial search for drug patent information already registered is available, but could only be done in Chinese. For example, using only the last three words of Palbociclib in Chinese ("柏西利" in "哌柏西利") resulted in the following search results:
Extensive information contained therein – good for FTO research

The “CN Orange Book” now has the following number of entries (as of 19 July 2021; the numbers in brackets below are those on 30 June 2021, one day after the platform became operational):

- 143 Chinese medicines (30)
- 448 chemical drugs (278)
- 60 biological drugs (39)

The substantial increase in the number of entries could be expected.

One amazing feature of the “CN Orange Book” is the inclusion of extensive data in each entry. Below is a screenshot of the entry in the “CN Orange Book” for the drug Palbociclib capsule 125mg (Note: only part of the entries of one of the three patents registered for this drug is shown below due to limit of the screen shot that could be taken):
It can be seen that in addition to the patent number, the following information in the “CN Orange Book” database entries is also available:

1) The granted patent itself is available for downloading at a link on the same page.
2) The claim number(s), and the relevant subject matter, are clearly identified.
3) The full-term expiry of the patent(s) is clearly identified.
4) Whether the patent has survived through invalidation is also specified in the note section.
On the other hand, there exists entries without the above extensive information of 1)-4), as shown below:

It should be noted that the relevant regulations, the NMPA Measures (see below) put the onus on the patentee/drug marketing approval owner to ensure the accuracy of the information registered on the platform, which requires the claim(s) covering what aspect of the drug to be identified (Article 4 of the NMPA Measures). Failure to do so could be legally liable (Article 15 of the NMPA Measures), while it is unclear what exactly are the punishments.

Having said so, after checking by myself, most of the entries in the “CN Orange Book” contain extensive information like the one of Palbociclib capsule 125mg above. Such information could be very useful for a freedom-to-operate (FTO) exercise. The immediate availabilities of the grant patent publication and the full-term expiry are already very useful. The specific identifications of the claim(s) and relevant subject matter are even more so.

By contrast, the equivalent FDA records only contain the US patent numbers, and nothing further. Below is the screenshot of Palbociclib capsule 125mg in the US FDA Orange Book records:
Restrictions on type of patents that could be registered

The “CN Orange Book” restricts that only the following types of patents could be registered for the respective drugs (Articles 5 and 12 of the NMPA Measures):

- Chemical drugs – chemical compound of the active ingredient; composition comprising the active ingredient; medical use
- Biological drug – sequence structure of the active ingredient; medical use
- Chinese medicine – composition; extracts from Chinese medicine; medical use

While not specified in the articles of the NMPA measures, the accompanying explanations of the NMPA measures specify that patents covering intermediates, metabolites, crystal form, method of manufacturing and testing methods are not considered as relevant patents under the patent linkage system, i.e. these patents should not be registered on the “CN Orange Book”. Therefore, the above types of patents would not be seen in the “CN Orange Book”.

Only Chinese company could register, and make entries on the platform

While everyone could access the platform to view information therein, in order to register entries on the platform (either for a drug, or making a declaration against a drug), one must register as a user on the platform. However, only a Chinese company could do so, as it is required to input the so-called "unified social credit codes" (compulsory) during registration, which are available to all Chinese companies. Further, the registration requires a CN mobile number to complete (for receiving a confirmatory text message).

See the screenshot below:
Declaration from a generic drug applicant against an innovative drug

For details on how such a declaration works, please refer to my articles below:
https://www.linkedin.com/pulse/cn-patent-inkage-measures-trial-finalized-issued-nmpa-toby-mak (This article talks about the finalized NMPA measures, which is based on the draft measures below)
https://www.linkedin.com/pulse/cn-drug-patent-registration-system-orange-book-opened-toby-mak (This article talks about the draft NMPA measures)

As a summary, when a generic drug applicant applies for drug marketing approval at the NMPA, the generic drug applicant is required to make a declaration of any one of the following four types:
I) That there is no patent information registered related to the drug.

II) That the patent(s) has already expired, or been declared invalid.

III) The date on which the patent(s) will expire, and that generic applicant promises that the generic drug will not go on the market until the expiry of the patent(s).
IV) That the patent(s) is not infringed, or should be declared invalid.

As of 19 July 2021, 11 such declarations have been announced on the CN platform. Ten of these are type I) declarations, while there is only one type III) declaration. This type III) declaration is the earliest one announced on 9 July 2021, with the screen shot below:

![Screen Shot](image)

The key is the type of declaration filed, in this case type III). It should also be noted that this page subdivides Declaration type IV) into the following two types:

- 4.1 - The patent(s) should be declared invalid.
- 4.2 – The generic drug does not fall within the scope of the patent(s).

The type of the declaration determines whether the drug patentee/marketing approval owner could take action against the subject generic drug marketing approval application. It appears only action could be taken against declaration type 4.2 (the generic drug does not fall within the scope of the patent(s)). While Article 7 of the NMPA measures could be literally read as allowing complaints to be filed at a court or the CNIPA for all 4 types of declarations, when combining with the relevant measures of the Supreme People’s Court and the CNIPA, it appears that there is a typographical error in Article 7 of the NMPA measures, and complaint could only be filed for declaration type 4.2. The first of such type 4.2 declaration is yet to be seen.
**Conclusion**

While the “CN Orange Book” is based on the US Orange Book (as required under the US-CN trade agreements 2021), the Chinese system has the following characteristics:

- The patent information in the Chinese system is much more extensive than that of the US.
- There is no drug data exclusivity information in the Chinese system.
- Action could only be taken against type 4.2 declaration (the generic drug does not fall within the scope of the patent(s)) in China.

There have been many changes in the last 3 weeks (from 29 June to 19 July 2021) on the “CN Orange Book”. For example, in the very beginning, the platform does not have different tabs for entries of chemical drug, biological drug, and Chinese medicine. Now individual tabs are available, making searching and counting much easier.

If you are an innovative drug owner, I am not surprised that you have already registered your drug patent information on the “CN Orange Book” to deter generic drug marketing approval application.

For others, including myself heavily involved in drug freedom-to-operate work, the “CN Orange Book” is a mountain full of treasures. Once the Chinese drug name is known (hint: have a look at the drug innovator’s Chinese website), the grant patent publication, claim(s) and subject matter(s) relevant (with clear indication on what claim is covering which subject matter), full term expiry, and invalidation information (if available) are all available in one place.

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