

“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.

“Unofficial” CN Orange Book user guide for pharmaceutical patents

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>. 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):

中国上市药品专利信息登记平台

Chinese medicine Chemical drugs Biological drugs

当前位置: 首页 > 专利信息公示列表 > 化药专利信息公示列表

中药专利信息公示 化药专利信息公示 生物制品专利信息公示

药品名称: 批准文号/注册号:

规格: 剂型:

序号	批准文号/注册号	药品类型	药品名称	规格	剂型	操作
1	国药准字J20190024	化学药品	盐酸芬戈莫德胶囊	0.5mg (按C19H33NO2计)	胶囊剂	查看
2	国药准字J20190002	化学药品	沙库巴曲缬沙坦钠片	以沙库巴曲缬沙坦计100mg(...	片剂	查看
3	国药准字J20190001	化学药品	沙库巴曲缬沙坦钠片	以沙库巴曲缬沙坦计50mg(...	片剂	查看
4	国药准字J20180077	化学药品	利伐沙班片	20 mg	片剂	查看
5	国药准字J20180076	化学药品	利伐沙班片	15 mg	片剂	查看
6	国药准字J20180075	化学药品	利伐沙班片	10 mg	片剂	查看
7	国药准字J20180021	化学药品	利司那肽注射液	10µg剂量注射笔 (绿色) : ...	注射剂	查看
8	国药准字J20180020	化学药品	利司那肽注射液	20µg剂量注射笔 (深紫红色...	注射剂	查看
9	国药准字J20171054	化学药品	沙库巴曲缬沙坦钠片	以沙库巴曲缬沙坦计100mg(...	片剂	查看

共 448 条 10条/页 < 1 2 3 4 5 6 ... 45 > 前往 1 页

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:

药品名称:	<input type="text" value="帕西利"/>	批准文号/注册证号:	<input type="text" value="请输入批准文号/注册证号"/>	<input type="button" value="Q 查找"/>
规格:	<input type="text" value="请输入规格"/>	剂型:	<input type="text" value="请输入剂型"/>	

序号	批准文号/注册证号	药品类型	药品名称	规格	剂型	操作
1	H20180042	化学药品	哌柏西利胶囊	100mg	胶囊剂	<input type="button" value="查看"/>
2	H20180041	化学药品	哌柏西利胶囊	75mg	胶囊剂	<input type="button" value="查看"/>
3	H20180040	化学药品	哌柏西利胶囊	125mg	胶囊剂	<input type="button" value="查看"/>

共 3 条 前往 页

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):

专利信息登记详情

相关专利号: ZL03802556.6 CN patent no. 专利名称: 2-(吡啶-2-基氨基)-吡啶并[2,3-d]噁啶-7-酮

专利权人: 沃尼尔·朗伯有限责任公司 专利被许可人:

专利授权日期: 2011-06-22

授权证明文件: 文件1: CN03802556.6_专利证书.pdf
文件2: CN03802556.6授权文本.pdf click to instantly download CN grant publication

上市许可持有人与专利权人

普通实施许可合同的被许可人

人的关系:	specific claim in the patent	subject matter of the claims	full term expiry	Invalidation history of the patent	
药品与相关专利权利要求的对应关系:	序号 权利要求项编号	专利类型	专利保护期届满日	状态	备注
	1 1-2	化学药品活性成分化合物专利	2023-01-09	有效	权利要求编号是按本专利无效宣告请求审查决定中维持有效的权利要求编号
	2 3	化学药品医药用途专利	2023-01-09	有效	权利要求编号是按本专利无效宣告请求审查决定中维持有效的权利要求编号
					权利要求编号是按本专利无效宣告

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:

The screenshot shows a web interface titled "专利信息登记详情" (Patent Information Registration Details). It displays the following information:

- 专利信息:**
 - 相关专利号: ZL03821144.0
 - 专利名称: 包含盐酸伐地那非三水合物的药物
 - 专利权人: 拜耳知识产权有限责任公司
 - 专利被许可人:
 - 专利授权日期: 2010-12-15
 - 授权证明文件: 文件1: 伐地那非片-ZL03821144.0-专利证书.pdf; 文件2: 伐地那非片-ZL03821144.0-法律状态.pdf; 文件3: 伐地那非片-ZL03821144.0-说明书权利要求书摘要.pdf
- 上市许可持有人与专利权人的关系:** 普通实施许可合同的被许可人
- 药品与相关专利权利要求的对应关系:** A table with 6 columns: 序号, 权利要求项编号, 专利类型, 专利保护期届满日, 状态, 备注. Row 1: 1, [blank], [blank], [blank], [blank], [blank].
- 上市许可持有人联系信息:**
 - 境内联系人: 刘红强
 - 境内联系电话: 010-65893290

A "关闭" (Close) button is located at the bottom right of the window.

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:

Patent and Exclusivity for: N207103

Product 003 PALBOCICLIB (IBRANCE) CAPSULE 125MG							
Patent Data							
Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
003	6936612	01/16/2023	DS	DP			02/26/2015
003	7208489	01/16/2023	DS	DP		Y	02/26/2015
003	7456168	01/16/2023			U-1998 U-2515		02/26/2015
003	10723730	02/08/2034	DS	DP			08/27/2020
003	RE47739	03/05/2027	DS	DP			12/19/2019

Exclusivity Data		
Product No	Exclusivity Code	Exclusivity Expiration
Your search did not return any results		

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:



1 填写认证信息

2 创建用户

3 完成注册

* 法人名称:	请输入您的法人名称 (企业/事业单位/社会组织名称)
* 法人类型:	请选择法人类型
* 统一社会信用代码:	请输入法人统一社会信用代码 Unified social credit code
* 法定代表人:	请输入法定代表人姓名
* 法定代表人证件类型:	请选择法定代表人证件类型
* 法定代表人证件号码:	请输入法定代表人证件号码
* 法定代表人手机号:	请输入法定代表人手机号(中国大陆手机号) CN mobile number
* 图形验证码:	请输入右侧图形验证码, 再获取短信验证码 
* 短信验证码:	请输入收到的短信验证码 <input type="button" value="获取短信验证码"/>

我已阅读并同意《政务服务平台注册协议》

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:

专利声明详情

申请人: 北京泰德制药股份有限公司
联系人: 张雨山
电子邮箱: zhangyush3@tidepharm.com
通讯地址: 北京市北京经济技术开发区科创八街19号院
联系电话: 010-67880648-1524

被仿制药等相关信息

药品名称: 厄帕西利胶囊 Name of drug
批准文号/注册证号: H20180040 Innovative drug registration no.
持有人名称: Pfizer Europe MA EEIG Owner's name

序号	登记的专利号	登记的权利要求项编号	专利声明类型	备注
1	ZL201010255766.6	1-4,5-6,9	3类	
2	ZL201110115074.6	1-2	3类	
3	ZL03802556.6	1-2,3,4	3类	

专利声明类型: 1类: 中国上市药品专利信息登记平台中没有被仿制药相关专利信息 (专利信息登记平台登记号、登记的专利号均填写“无”); 2类: 中国上市药品专利信息登记平台收录的被仿制药相关专利权已终止或者被宣告无效, 或者仿制药申请人已获得专利权人相关专利实施许可 (在备注中注明相应的具体情形); 3类: 中国上市药品专利信息登记平台收录有被仿制药相关专利, 仿制药申请人承诺在相应专利权有效期届满之前所申请的仿制药暂不上市; 4.1类: 中国上市药品专利信息登记平台收录的被仿制药相关专利权应当被宣告无效, 4.2类: 仿制药未落入中国上市药品专利信息登记平台收录的被仿制药相关专利权保护范围。

Declaration type 4.1 - the patent(s) should be declared invalid
Declaration type 4.2 - the generic drug does NOT fall within the scope of the patent(s)

× 关闭

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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