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IP Insights

First Non-Contentious and Contentious CN Patent Linkage Declaration from Generic Drug Applicant

Toby Mak

Patent Attorney, Civil and Administrative Agent Ad Litem

Toby Mak is a patent attorney at Tee & Howe Intellectual Property Attorneys. Dr. Mak has a Ph. D in Chemistry and more than 20 years of experience in IP affairs. He has substantive experiences in handling both contentious and non-contentious matters, including prosecution, invalidation and enforcement. He is also recommended by All-China Patent Attorneys Association to appear both in civil and administrative courts. Dr. Mak has served many clients of different technical fields including local and overseas research institutes and universities, multinational power tool and semiconductor companies, adhesives manufacturers, Video-on-demand Company, and biotech companies.

Dr. Mak is current co-chair of the AIPLA's IP Practice in China committee, active member of the Asian Practice committee of the IPO, and a foreign member of the UK CIPA.

I. Relevant Mechanism

As required by the CN-US phase I trade agreement, China has been introduced a drug patent linkage mechanism similar to the US, providing an early dispute resolution mechanism between the drug marketing approval holder (MAH) and the generic drug applicant (DGA). Specifically, for a drug patent registered by the MAH directed to a drug, when the DGA applies for the generic drug marketing approval, the DGA is required to make any one of the following four types of declaration:

1. That there is no patent information registered related to the drug.
2. That the patent(s) has already expired, or been declared invalid.
3. 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).
4. That the patent(s) is not infringed, or should be declared invalid.

Types 1 to 3 are non-contentious, while type 4 is contentious. Declaration type 4 is further subdivided 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 MAH 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 China National Medical Products Administration (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 effect of such an action against declaration type 4.2 is that if the generic drug was determined by the court or CNIPA to fall within the scope of the relevant patent, the generic drug marketing approval process would be suspended until 9 months before the expiry of the relevant patent.

II. First Patent Linkage Declaration (Non-Contentious)

The first patent linkage declaration was filed by Beijing Taide Pharmacy Limited Company against MAH Pfizer. The drug at issue is Palbociclib capsule 125mg, for treating HR-positive and HER2-negative breast cancer. The declaration was accepted on 9 July 2021, 4 days after the CNIPA and the Supreme Court patent linkage measures are announced.

While this is the first patent linkage declaration in China, it is only a **non-contentious** type 3 declaration, which means that the generic drug applicant says that they would only put their drug onto the market after the patents have expired, which would be 9 January 2023.


专利声明详情

化学仿制药/中药同名同方药/生物类似药信息

药品名称： 哌柏西利胶囊　　药品类型： 化学药品

剂型： 胶囊剂　　规格： 125mg

申请人： 北京泰德制药股份有限公司　　通讯地址： 北京市北京经济技术开发区科创八街19号院

联系人： 张雨山　　联系电话： 010-67880648-1524

电子邮箱： zhangysh3@tidepharm.com

被仿制药等相关信息

药品名称： 哌柏西利胶囊　　批准文号/注册证号： H20180040

持有人名称： Pfizer Europe MA EEIG

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	

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III. First Contentious Patent Linkage Declaration

On 23 July 2021, the first **contentious** CN patent linkage declaration was announced, directed to the drug dapagliflozin 5 and 10 mg, with AstraZeneca as the drug marketing approval owner in China.

专利声明详情

药品名称： 达格列净片　　药品类型： 化学药品

剂型： 片剂　　规格： 5mg

申请人： 江苏豪森药业集团有限公司　　通讯地址： 连云港经济技术开发区东晋路9号

联系人： 王瑞军 李琴　　联系电话： 13951499819 0518-83099366

电子邮箱： 13951499819@163.com liq1@hspharm.com

被仿制药等相关信息

药品名称： 达格列净片　　批准文号/注册证号： H20170117、H20170118

持有人名称： AstraZeneca AB

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	ZL 200910158686.6	1，2，3，14，15，16	3类	
2	ZL 200880016902.7	8	4.2类	组合物的API与该专利不同
3	ZL 201210201489.X	1，2，3，7，8，9	4.2类	组合物的API与该专利不同
4	ZL 200780024135.X	9	4.2类	API与该专利不同

专利声明详情

药品名称： 达格列净片　　药品类型： 化学药品

剂型： 片剂　　规格： 10mg

申请人： 江苏豪森药业集团有限公司　　通讯地址： 连云港经济技术开发区东晋路9号

联系人： 王瑞军 李琴　　联系电话： 13951499819 0518-83099366

电子邮箱： 13951499819@163.com liq1@hspharm.com

被仿制药等相关信息

药品名称： 达格列净片　　批准文号/注册证号： H20170119、H20170120

持有人名称： AstraZeneca AB

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	ZL 200910158686.6	1，2，3，14，15，16	3类	
2	ZL 200880016902.7	8	4.2类	组合物的API与该专利不同
3	ZL 201210201489.X	1，2，3，7，8，9	4.2类	组合物的API与该专利不同
4	ZL 200780024135.X	9	4.2类	API与该专利不同

It is interesting to note that the generic drug applicant Jiangsu Hansoh Pharmaceutical Group Co., Ltd. (hereinafter referred to as "Hansoh") filed a type 3 declaration against CN200910158686.6 directed to the chemical compound of the active pharmaceutical ingredient API dapagliflozin itself, i.e. Hansoh undertakes that they would only put their drug onto the market after CN200910158686.6 has expired on 15 May 2023 (CN200910158686.6 is a divisional application from CN03811353.8).

On the other hand, Hansoh filed type 4.2 declarations against the following 3 CN patents, i.e. Hansoh declared that their generic drug does not fall within the scope of the following 3 CN patents that are directed to specific formulations and medical uses:

1. CN200880016902.7 (full term expiry 21 March 2028) - specific formulation comprising the API in the form of dapagliflozin propylene glycol hydrate, microcrystalline cellulose, lactose, crospovidone, silicon dioxide, magnesium stearate, with each components presents in respective specific amounts (claim 8).

2. CN200780024135.X (full term expiry 21 June 2027) - Medical use (Swiss-type claim) of dapagliflozin propylene glycol hydrate with specific crystalline structure (note: patents directed to crystalline structure of a drug per se should not be registered in the CN Orange Book) in treating diabetes, insulin resistance, hyperglycemia, hyperinsulinemia, elevated blood levels of fatty acids or glycerol, hyperlipidemia, dyslipidemia, obesity, hypertriglyceridemia, or diabetic complications (claim 9).

3. CN201210201489.X (full term expiry 21 March 2028) - specific formulation comprising the API in the form of dapagliflozin propylene glycol hydrate with a specific dosage regime (claim 1), with further components including bulking agent, binder, disintegrant, and so on (claims 2 and 3), and the medical uses of such specific formulation (Swiss-type claims) for treating diabetes.

That is, Hansoh chose to challenge the patents directed to specific formulations comprising the API dapagliflozin propylene glycol hydrate, and the medical use of the crystalline API. Comparing with the chemical compound patent CN200910158686.6 (which Hanson chose to deal with with a type 3 declaration), there is higher chance to get around these formulation and medical use patents, for example by not using dapagliflozin propylene glycol hydrate, but uses dapagliflozin itself (whether this would be caught by equivalence is another question). In fact, Hanosh declared that the API in their generic drug is different from that in these 3 CN patents, i.e. dapagliflozin propylene glycol hydrate.

AstraZeneca has had until 6 September 2021 (45 days from 23 July 2021) to file a complaint against Hansoh's type 4.2 declaration against the 3 CN patents above at the Beijing IP Court, or at the CNIPA. Failure to do so would result in that the drug marketing approval application would be processed as normal by the NMPA as usual, i.e. without any delay.

If AstraZeneca filed the complaint and was accepted (by the Beijing IP Court, or the CNIPA), and a decision was made within 9 months from the date of acceptance of the complaint:

- if the decision was in favor of AstraZeneca, the drug marketing approval would be delayed to 9 months before the expiry of the above three patents, i.e. maximum delay up to 2028.

- if the decision was not in favor of AstraZeneca or not with 9 months, the drug marketing approval would be processed as normal.

However, as Hanosh undertakes a type 3 declarations against CN200910158686.6, the earliest date that Hanosh could put their generic drug on the market in China is 15 May 2023.

Let's wait and see whether AstraZeneca would file a complaint, in which the biggest obstacles may be to get documents including Power of Attorney to be notarized and legalized.

Address: Suite 5-12, 5th Floor, Tower W1, The Tower Offices, Oriental Plaza, No.1 East Chang'an Avenue, Dongcheng District, Beijing 100738, China

Tel:(86 10) 8529 5526

Fax:(86 10) 8529 5528

Email:teehowe@teehowe.com

Website:www.teehowe.com

Wechat Account QR Code:

Beijing

Japan

Germany

Changsha