加拿大药品专利诉讼：给中国制药厂商的建议

Tips for Chinese pharmas on patent litigation in Canada

最近 20 年里加拿大的药品专利诉讼案件在专利诉讼中占主导地位，其中原因包括仿制药业在国家医疗保健系统的重要地位；更重要的是，加拿大独特的关于药品专利的法律制度推进了该类案件的增长。

本文着重阐述几个关于加拿大药品专利诉讼特有的程序上和实质性的问题，供中国制药厂商在考虑进入加拿大市场时参考。

加拿大体系

加拿大药品专利诉讼程序不套用 Hatch-Waxman 法案诉讼（美国体系）。在加拿大，专利药（合规通知）法规将仿制药的上市申请审批与创新药商的相应药品专利链接。如果仿制药商的上市申请是基于相应专利创新药的上市申请，该仿制药商必须克服创新药商在专利注册簿上登记的所有专利，否则卫生部长无权将注册审批，即合规通知（notice of compliance），授予仿制药商。在这一点上，加拿大体系类似于美国体系；除此之外，加拿大体系与美国体系在程序上有很大的不同。

最显著的是，专利药（合规通知）诉讼是申请诉讼（application），只采用书面宣誓证据（即没有在法庭上的口头证词），其判决是确定卫生部长是否能授予仿制药商合规通知。因此，专利药（合规通知）诉讼的判决不是对专利侵权及有效性的最终判决。败诉方可以自行选择对同一专利重新展开全面诉讼（action）。事实上，因为加拿大联邦法院一般在这些随后的全面诉讼开始后两年之内开庭审理，这已经成为近期的趋势。后期全面诉讼对专利的判决跟前期诉讼的判决不一致也是有可能的。近期的一个例子是奥贝泰克公司告辉瑞爱尔兰制药涉及万艾可®（枸橼酸西地那非）专利。仿制药商奥贝泰克公司在专利药（合规通知）诉讼上败诉，但在随后的专利弹劾案胜诉。

鉴于专利药（合规通知）诉讼之后是否有另一轮诉讼的不确定性，中国制药厂商在做加拿大上市申请时应将专利药（合规通知）诉讼的费用和全面诉讼的高额诉讼费都纳入预算内。

加拿大体系的另一独特之处是，在专利药（合规通知）诉讼中败诉的专利权所有人，特别是在专利被认定无效的情况下，通常不能对随后的仿制药商进行专利药（合规通知）诉讼。随后的仿制药商可受益于第一个仿制药商的胜诉来获得合规通知。因此，中国仿制药商可考虑不总是第一个挑战专利。

In Canada, pharmaceutical patent cases have dominated patent litigation for the past two decades. This is partly due to the significant role played by the generic pharmaceutical industry in the country's healthcare system. More importantly, Canada's unique legal framework governing pharmaceutical patents has propelled the proliferation. This article highlights a few unique procedural and substantive issues regarding Canada's pharmaceutical patent litigation, which may be of interest to Chinese pharmaceutical companies considering entering the Canadian market.

CANADIAN SYSTEM

Canada does not have Hatch-Waxman Act litigation, as per the American system. In Canada, the Patented Medicines (Notice of Compliance) Regulations link the ability of a generic pharmaceutical manufacturer to obtain regulatory approval to market its product, to an innovator's patents. The Minister of Heath cannot grant regulatory approval, called a notice of compliance (NOC), to a generic seeking approval for its product based on a comparison with an innovator's product, until the generic has addressed all patents listed by the innovator on the patent register for the brand name product. In this regard, the Canadian system is similar to the American system. Beyond this, the Canadian system is quite different procedurally.

Most significantly, litigation under the regulations – a PM (NOC) proceeding – is an application based on a paper record of affidavit evidence (i.e., no trial with live witnesses) and determines only whether the Minister of Health can issue an NOC to the generic. Decisions from the PM (NOC) proceedings are not final determinations of patent infringement or validity. The losing party is free to commence a fresh action re-litigating the same patent.

In fact, this has become a recent trend, as these subsequent actions are generally heard by Canada's Federal Court within two years of commencement. It is possible that a different outcome can be reached in the subsequent action. A relatively recent example of a generic

专利承诺原则

专利承诺原则是加拿大专利法特有的。如果专利说明书明确承诺发明的实用性，而专利权所有人不能证明在加拿大申请日该实用性已被证明或合理预测，则该专利无效。加拿大最高法院在“奥贝泰克公司告惠康基金会有限案”的判决书中对合理预测的判断有下述阐诉：

首先，必须有用于预测的事实基础。其次，发明人必须在该专利申请日提供事实依据和想获得的结果之间清晰并合理的推导关系。第三，必须有适当的信息公开。

满足适当公开的这个条件给专利权所有人带来很大的困扰。加拿大法庭将这一条件解释为专利说明书必须公开用于预测的事实基础以及拥有清晰并合理的推导关系（有时被称为增强的专利公开要求）。已经有一些药品专利因不满足承诺原则被判决无效，包括如赛诺菲 - 安万特雷米普利（ALTACE®）化合物专利和阿斯利康的埃索美拉唑（耐信 ®）化合物专利。加拿大最高法院将在 2016 年 11 月进行对阿斯利康关于埃索美拉唑专利无效上诉的听证。该听证预计将回答以下问题：(1) 专利承诺原则是否合理存在？(2) 加拿大判断实用性的标准是什么？(3) 增强的专利公开要求适用于所有专利，还是局限于新用途专利？

作为全球专利策略的一部分，中国创新药厂商要想获得加拿大专利并从专利药（合规通知）法规中受益，就应该审查正在申请的专利；弱化专利承诺语言，例如将“会”改成“兴许”或“可能”；并有一组范围窄的权利要求，该组要求的实用性在说明书中有合理支持或已在加拿大申请日时被证明。这点对生物技术、药品和化学专利尤其重要。

非侵权替代

在加拿大，非侵权替代（non-infringing alternative）在计算专利侵权损害赔偿时是一个法律相关的考虑因素（奥贝泰克公司诉默克公司案）。侵权者必须建立至少下列事实要素才能成功证明非侵权替代的存在：(1) 非侵权替代是一个真正的替代品，因此是一个真实的选择；(2) 非侵权替代在经济上是可行的；(3) 侵权人有可能会出售非侵权替代；(4) 侵权人实际上将会出售非侵权替代。

近年来，中国的仿制药商，作为活性药物成分或最终产品的供应商，在加拿大的仿制药行业日趋活跃。因此，它们可能成为加拿大专利侵权诉讼中的被告。如果被提起诉讼，中国仿制药商应考虑提出在计算专利侵权损害赔偿时非侵权替代的存在。因此，妥善保留证明非侵权替代存在的上述事实要素的文献记录就十分重要。

succeeding in a patent impeachment action following its loss in a PM (NOC) proceeding involved Pfizer's VIAGRA® (sildenafil citrate) in *Apotex Inc v Pfizer Ireland Pharmaceuticals*.

Given the uncertainty of litigation after a PM (NOC) proceeding, Chinese pharmaceutical companies seeking approval for their products in Canada should budget for the high costs of a fully-fledged action, in addition to the litigation costs under the regulations.

Another unique feature of the Canadian system is that a patentee who loses a PM (NOC) proceeding against one generic, especially on validity, is generally prohibited from litigating against subsequent generics under the regulations. Subsequent generics may benefit from a first generic's success in obtaining an NOC. Hence, a Chinese generic may not always want to be the first patent challenger.

THE PROMISE DOCTRINE

Unique to Canadian patent law is the "promise of the patent" doctrine. If a patent sets out an explicit promise of utility, the patent will be invalid if the promised utility is not demonstrated or soundly predicted as of the Canadian filing date. The Supreme Court of Canada in *Apotex Inc v Wellcome Foundation* set out the test for sound prediction as follows: Firstly, there must be a factual basis for the prediction. Secondly, the inventor must have, at the date of the patent application, an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis. Thirdly, there must be proper disclosure.

The last element of the sound prediction test is particularly troublesome. Canadian Courts have interpreted this element as requiring that the patent specification must disclose the factual basis and the line of reasoning (sometimes referred to as a heightened disclosure requirement).

Several pharmaceutical patents have been found invalid on the promise doctrine, including Sanofi-Aventis' ramipril (ALTACE®) compound patent, and AstraZeneca's esomeprazole (NEXIUM®) compound patent. The Supreme Court of Canada will hear AstraZeneca's appeal concerning the esomeprazole patent in November 2016. This hearing is expected to resolve the following issues: (1) does the promise doctrine properly exist?; (2) what is the correct applicable standard for utility in Canada?; and (3) does a heightened disclosure requirement apply to all patents or only to new use patents?

As part of their global patent strategy, Chinese innovators wishing to procure Canadian patents and benefit from the regulations should review their pending patent applications to soften the promise language, e.g. by changing the words "will" to "may" or "can", and to have a narrow set of claims whose utility can be reasonably supported based on the disclosure, or has been demonstrated as of the Canadian filing date. This is especially important for biotech, pharmaceutical and chemical patents.

NON-INFRINGING ALTERNATIVES

In Canada, the availability of a non-infringing alternative (NIA) is a legally relevant consideration when calculating damages for patent infringement (*Apotex Inc v Merck & Co*). An infringer must establish at least the following factual elements to succeed: (1) the NIA was a true substitute and thus a real alternative; (2) the NIA was economically viable; (3) the infringer could have sold the NIA; and (4) the infringer would actually have sold the NIA.

In recent years, Chinese generics have become increasingly active in Canada's generic pharmaceutical industry as suppliers of active pharmaceutical ingredients or final products. Hence, they are exposed to patent infringement actions in Canada. If sued, Chinese generics should consider asserting the availability of an NIA in any damage calculations. In this regard, it is important to keep good documentary records reflecting the above factual elements for an NIA.

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