Canada's Drug Linkage Regulations Finally Grow Up – Becoming a Full Action

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Canada is taking steps to streamline drug patent owners' ability to enforce their patents. These steps should reduce the multiplicity of litigation between brand name and generic drug companies.

Background - Proactive Patent Enforcement With the NOC Regulations

The Canadian *Patented Medicine (Notice of Compliance) Regulations* ("**NOC Regulations**") allow a patent owner to apply to Federal Court to keep a generic company's potentially infringing medicine off the market ***before*** the generic company receives Health Canada approval to sell its medicine. The NOC Regulations are informally called "linkage regulations" because they link regulatory approval a drug to the condition precedent of passing an initial review of patent issues.

Health Canada is the Canadian counterpart to the US FDA. The Health Canada approval for a brand name company or generic company to sell a medicine is called an **NOC**. Prior to the NOC Regulations, the patent owner often had to chase the generic company ***after*** the medicine was already on the market. Since interlocutory injunctions are difficult to obtain and it takes a long time to bring a patent infringement case through to trial, there are significant benefits to a patent owner in keeping a generic company from entering the market.

The NOC Regulations operate by allowing a patent owner to file an application in court to request an order *prohibiting the government from issuing an NOC to the generic company* (note the wording of the order, it is *not* a determination of patent infringement). In order to take advantage of the NOC Regulations, the patent owner must list its patents on a Health Canada "Patent Register" within strict time limits. If the patent owner cannot add its patent to the Patent Register, then there is no trigger for the NOC Regulations, and the patent owner is back to suing for conventional patent infringement *after* the generic company is on the market.

The Problems with NOC Proceedings

The NOC Proceedings are not final determinations of patent validity or infringement. They were intended to be summary proceedings that are quick, straightforward and efficient court assessments of patent issues to determine whether the generic drug company can get its marketing authorization and go on the market. However, NOC Proceedings became complex and cumbersome, with many issues in play and much expert evidence. Once the NOC Proceeding was over, brand name companies often lost their right of appeal because the generic company got its NOC, making the appeal moot. There was also a multiplicity of litigation because either the brand name or the generic company can start separate patent litigation for a full determination of patent validity and infringement issues. The separate litigation could be either concurrent or subsequent to an NOC Proceeding.

NOC Proceedings Grow Up and Become Full Actions

Canada and Europe recently signed off on the Comprehensive Economic and Trade Agreement ("**CETA**"). The Canadian federal government then introduced on October 31, 2016, a Bill that will implement portions of CETA and also provide regulation-making authority to permit the replace the current summary NOC Proceedings with full patent infringement and validity actions[1]. This will result in final determinations on infringement and validity issues[2]. This should reduce the multiplicity of litigation. It should also permit brand name companies to appeal trial decisions.

Next Steps

We do not yet know the details of the new regulations. However, the change from a summary application process to a full action should make the Canadian system look more like the US system for ANDA litigation. This new system should be a reasonable compromise for both generic and brand name drug companies.

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[1] Bill C-30, An Act to implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its Member States and to provide for certain other measures, First Session, Forty-second Parliament,64-65 Elizabeth II, 2015-2016 (first reading October 31, 2016).

[2] S. 55.2(4).