Goodmans LLP Update

Health Canada Rejects Application for Additional Patent Protection Under Certificate of Supplementary Protection Regime

A recent decision by Health Canada to decline an application by a pharmaceutical company for a Certificate of Supplementary Protection (CSP) may have significant repercussions for holders of patents for pharmaceutical products hoping to take advantage of an additional two-year period of patent protection now available for eligible drugs.

An application challenging Health Canada's decision was commenced in the Federal Court. A decision, if rendered, may have significant implications for both originator and generic drug companies.

Canada's CSP Regime

To meet Canada's obligations under the Comprehensive Economic and Trade Agreement (CETA), the *Patent Act* was amended in 2017 to create a legal framework for the issuance of CSPs. Shortly thereafter, the government enacted the *Certificate of Supplementary Protection Regulations* (the "***Regulations***"), which govern the issuance and administration of CSPs.

If granted, a CSP provides an additional period of protection under the *Patent Act* of up to two years for eligible pharmaceutical products. The CSP regime was intended to partly compensate patent holders for the time it takes to obtain marketing approval for a drug containing patented medicinal ingredients. The scope of protection provided by a CSP can be no broader than the protection afforded by the patent that claims the underlying medicinal ingredient.

The *Patent Act* and the *Regulations* set out the conditions to be met for a CSP to be granted. Among other things, the CSP must pertain to an eligible *medicinal ingredient* and an eligible *patent*.

An eligible medicinal ingredient must have received a Notice of Compliance (NOC) under the *Food and Drug Regulations* after the CSP regime came into force in September 2017. In addition, the NOC must have been the first authorization for sale issued for that medicinal ingredient. The *Regulations* contain specific rules as to how to identify the applicable medicinal ingredient. For example, certain variations of medicinal ingredients are deemed to be the "same" medicinal agreement under the *Regulations* for the purpose of determining whether the medicinal ingredient in question has previously been authorized for sale.

An eligible patent must meet the requirements of section 106 of the *Patent Act* and subsection 3(2) of the *Regulations*. Among other requirements, an eligible patent must pertain to "the medicinal ingredient or combination of all the medicinal ingredients contained in a drug" for which an NOC was issued after the CSP regime came into force.

The *Regulations* also set out various other requirements, including rules relating to the timing and form of applications for CSP.

Pursuant to the *Regulations*, the responsibility for administering the CSP regime lies with the Minister of Health.

The ViiV Healthcare ULC ("ViiV") Application

In an application commenced on February 22, 2019, ViiV challenged the Minister of Health's decision to refuse to issue a CSP in respect of one of its products marketed under the brand name JULUCA.

JULUCA, a tablet indicated as a complete regimen to replace current antiretroviral regimens for the treatment of human immunodeficiency virus (HIV), received an NOC from Health Canada on May 18, 2018. It contains two medicinal ingredients, dolutegravir and rilpivirine.

ViiV is the owner of Canadian Letters Patent 2,606,282 (the "**282 Patent**") which contains 437 claims, one of which is for dolutegravir. It does not appear that the 282 Patent contains a claim for rilpivirine, the other medicinal ingredient in JULUCA.

ViiV applied for a CSP in respect of JULUCA, relying on the claim for dolutegravir in the 282 Patent. The Minister refused to issue the CSP, apparently on the basis the 282 Patent "contains claims directed toward one of the medicinal ingredients contained in JULUCA…[but] does not pertain to the combination of medicinal ingredients dolutegravir and rilpvirine in the manners prescribed by subsection 3(2) of the *CSP Regulations*".

It appears the Minister's position is that, to be eligible for a CSP in the case of a drug containing a combination of medicinal ingredients, the patent must claim the combination and not just one of the two medicinal ingredients.

ViiV alleges the Minister's position is based on an incorrect interpretation of the requirements under the *Regulations* and the *Patent Act*.

Potential Consequences of ViiV's Application

If this case proceeds to a hearing, it could result in the first judicial interpretation of the new CSP legislative and regulatory regime.

The additional period of protection provided by CSPs was an important component to the CETA framework governing pharmaceuticals. By providing additional protection of up to two years for eligible drugs containing patented medicinal ingredients, CSPs could have significant impact on both brand name and generic pharmaceutical companies and on the cost for prescription drugs in Canada over the long term. The availability of CSPs and the interpretation of the CSP regime are important issues for the court to consider.

Goodmans will continue to monitor the progress of this case and any others that might have an impact on CSPs in Canada. Should you have any questions, please contact any member of our Intellectual Property Group.

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