Rx IP - Court Decision | Rx IP - Regulatory

JULUCA CSP application remitted to Minister of Health for reconsideration.

July 29, 2020

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In a decision dated July 10, 2020, the Federal Court in *ViiV Healthcare ULC v The Minister of Health*, 2020 FC 756 remitted another application for a Certificate of Supplementary Protection (CSP) to the Minister of Health for reconsideration. This is the second Court decision on CSPs, and the second time the Court has sent the matter back to the Minister for reconsideration. The first decision on CSPs was reported here.

The decision is important as it may expand the scope of patents that may be eligible for CSP protection; namely, to include patents that claim only one or some of the medicinal ingredients in a drug comprising a combination of medicinal ingredients.

ViiV had sought a CSP for Canadian Patent No. 2,606,282 – which claims dolutegravir, but does not claim a combination of dolutegravir and rilpivirine. The CSP application was based upon **JULUCA**, which contains a combination of **dolutegravir** and **rilpivirine**.

Subsection 3(2) of the *CSP Regulations* sets out which patents may be eligible for a CSP pursuant to section 106 of the *Patent Act*, and insofar as combinations are concerned, refers to the patent claiming the "combination of ***all*** the medicinal ingredients contained in the approved drug". The Minister had found that:

[14] …"where the approved drug contains a combination of medicinal ingredients, [an eligible] patent must include a claim for the combination of all the medicinal ingredients, a claim for the combination of all the medicinal ingredients as obtained by a specified process, or a claim for a use of the combination of all the medicinal ingredients" in order to meet the requirements of CSPR section 3(2)…

The Minister's conclusion was based upon the Regulatory Impact Analysis Statement accompanying the publication of the *CSP Regulations*, and Health Canada's own Guidance Document.

CSPs were introduced further to Canada's commitments under the *Canada-European Union Comprehensive Economic and Trade Agreement* (CETA). ViiV had argued that the provisions in the *Patent Act* and *CSP Regulations* relating to CSPs had to be interpreted in a manner consistent with CETA, Article 20.27 of which requires that a basic patent protect "a product as such". Viiv argued that "a 'basic patent' includes a patent containing a claim to at least one medicinal ingredient contained in a combination drug because that patent, even though it only lists one ingredient in the combination, nonetheless protects the entire product; in other words, it protects the product 'as such'".

Justice Fuhrer found that the Minister failed to adequately consider ViiV's submissions regarding the proper interpretation of the *Patent Act* and *CSP Regulations* relating to new combinations of medicinal ingredients. Because the Minister failed to consider ViiV's CETA submissions adequately, the Minister's decision denying a CSP for JULUCA was unreasonable and remitted the matter to the Minister for redetermination.

This decision is subject to appeal.

Should you have any questions, please do not hesitate to contact a member of the Pharmaceutical Litigation group.

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