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Business

Refusal of Certificate of Supplementary Protection unreasonable says Federal Court

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(December 2, 2021, 8:39 AM EST) -- For the third time since the Canadian Certificate of Supplementary Protection (CSP) regime came into force, the Federal Court has reviewed the decision to refuse a CSP application. The decisions in *ViiV Healthcare ULC v. Canada (Minster of Health)*, 2020 FC 756 (JULUCA), *Canada (Minster of Health) v. GlaxoSmithKline Biologicals S.A.*, 2021 FCA 71 (SHINGRIX), and most recently in *Merck Canada Inc v. Minister of Health,* 2021 FC 1015 (BELSOMRA), highlight the critical importance of considering the objectives underlying the CSP Regime during the application process.

On Oct. 30, 2016, Canadian and European Union (EU) leaders signed the Comprehensive Economic and Trade Agreement (CETA), resulting in the implementation of Canada's CSP regime, which aims to promote research into new medicinal ingredients or new combinations of medicinal ingredients and to give an incentive to put them into practice for the benefit of the public. At heart of JULUCA, SHINGRIX, and now BELSOMRA were issues of statutory interpretation of CSP eligibility provisions. These decisions have emphasized the importance of considering the text of CETA as well as the context and purpose of the provisions in the *Patent Act* and *CSP Regulations* in such interpretations.

In BELSOMRA, Merck sought judicial review of the minister of health's refusal to issue a CSP for suvorexant, the medicinal ingredient in Merck's drug product BELSOMRA.

Two CSP eligibility requirements were at issue in this decision. The first is the "authorization for sale requirement," which requires an authorization for sale to have been issued for the medicinal ingredient, or combination of medicinal ingredients, after the CSP provisions came into force in September 2017. The definition of "authorization for sale" includes a Notice of Compliance (NOC), but also covers any authorizations under the *Food and Drugs Act*, save for certain exclusions. The second eligibility requirement at issue is the "timely submission requirement," which requires a Canadian New Drug Submission (NDS) to be filed within 12 months after authorization is first sought in a prescribed country. The goal of the timely submission requirement is to incentivize the early introduction of innovative drugs into the Canadian market.

Merck first filed an NDS for Canadian approval of BELSOMRA on Nov. 15, 2012, which was within 12 months after authorization was first sought in the U.S. (one of the prescribed countries). Health Canada issued a Notice of Deficiency, citing concerns that the NDS contained insufficient information about the benefit/risk profile of suvorexant, and that additional clinical trial data were required. Merck withdrew this NDS in February 2014. Merck filed a second NDS in 2016 with additional safety evidence. It was as a result of this second NDS that the NOC for BELSOMRA was issued in November 2018. In 2019, Merck applied for a CSP, identifying the NOC to fulfil the "authorization for sale requirement," and the first NDS filed in 2012 to fulfil the "timely submission requirement."

Health Canada, on behalf on the minister, gave the preliminary view that Merck was not eligible to receive a CSP, because it did not meet those two requirements. In response, Merck filed submissions including statutory interpretation arguments that it met the authorization for sale requirement since it obtained an NOC for BELSOMRA in November 2018. Further, Merck met the timely submission requirement since it filed an NDS in Canada within 12 months of the first filing for authorization in the U.S. Merck also argued that the preliminary decision was contrary to the object and purpose of the *Patent Act* and *CSP Regulations*, which was to promote innovation and investment in new drugs in Canada by compensating innovators for patent term lost during research and while obtaining market authorization.

In August 2019, the minister refused Merck's application, finding that the first NDS, which was withdrawn and did not receive an NOC for BELSOMRA, could not satisfy the authorization for sale requirement. Further, the second NDS, which did receive an NOC, did not meet the timely submission requirement. However, in its decision, the minister did not address the context or purpose of the CSP regime set out in the *Patent Act* and *CSP Regulations*.

At the Federal Court, the only issue raised in Merck's application for judicial review was whether the minister's decision to deny Merck's application for a CSP for BELSOMRA was reasonable. In this case, the minister's failure to consider the context and purpose of the CSP regime in the interpretation of CSP eligibility requirements was fatal, resulting in Merck's CSP application being remitted for redetermination. Ultimately, the Federal Court lost confidence in the minister's decision due to the minister's failure to consider the context and purpose of the provisions, as well as the central role of CETA in the context and enactment of the provisions. The Federal Court emphasized that it was *not* approving or disapproving of either the minister's interpretations and arguments or those of Merck. Rather, the minister's decision was unreasonable because it failed to meaningfully account for a key argument raised by Merck pertaining to a relevant issue of statutory interpretation. The minister's decision was set aside, and Merck's CSP application was remitted for redetermination.

This decision, along with JULUCA and SHINGRIX, emphasizes the importance of the policy and intent behind the CSP regime, along with Canada's international obligations underlying the CETA, in the consideration of CSP eligibility.

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